August 8, 2018

UNIQA DENTAL LTD.
% Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22815 Ventura Blvd.
Woodland Hills, California 91364

Re: K180598
Trade/Device Name: UNIQA® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 14, 2018
Received: May 23, 2018

Dear Daniela Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 - Indication for Use Statement

510(k) Number (if known):

K180598

Device Name:

UNIQA® Dental Implants System

Indications for Use (*Describe*)

Indications for Use:

UNIQA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments.

Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

Type of Use (Select one or both, as applicable)

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use(21 CFR 801 Subpart

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K180598

1	Type of Submission Premarket Notification (21 CFR 807.90(e)) 510(k) Traditional	
2	Submission Owner	UNIQA DENTAL LTD. Dima Goberman - CEO 26 Tom Lantos blvd., Alon Center Netanya 4276001 Israel Tel : 972-77-7827367 Fax : 972-73-7372636
3	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22815 Ventura blvd. Woodland Hills, CA 91364 Phone: 1-213-787-3027 Email: sterlingmedical2017@gmail.com
4	Date Prepared	Tuesday, August 7, 2018
5	Device Trade Name	UNIQA® Dental Implants System
6	Regulation Description	Endosseous Dental Implants Abutment
7	Classification	Primary Product Code: DZE Device Name : Implant, endosseous, root-form Regulation No : 872.3640 Class : II Panel : Dental Secondary Product Code: NHA
8	Reason for the Premarket Notification Submission :	New Device
9	Identification of Legally Marketed Predicate Devices:	

Primary Predicate:

MIS Implant Technologies Ltd Implants System K040807;

Reference Devices:

MIS Implant Technologies Ltd Implants System K163349;

Astra Tech AB OsseoSpeed TX K101732

Nobel Biocare Multi Unit Abutment K072570;

A.B. Dental Devices Ltd K132125, K112440;

Dentin Dental Implants System K120530;

in terms of intended use, indication for use, raw material, technological characteristics and performance. The primary predicate and referenced devices are Class II medical devices.

10 Device Description: :

UNIQA® Dental Implant System is consist of endosseous form dental implants, internal hex implants, tapered design; cover screws, healing caps and abutment systems; The Dental Implants provided in two types of design:(a) Conical Hex; (b) Internal Hex; Each implant design is available in two options of surface treatment (1) Pure & Porous, P&P - which consists of Hydroxyapatite and Calcium Phosphates; or (2) SBA - which consists of sand blast large particles with acid etched;

Dental Implants:

Conical Implant, Pure & Porous, P&P -

Measurements: Diameters 3.3, 3.75, 4.2, 5.0 mm with lengths 8, 10, 11.5, 13, 16 mm;

Conical Implant, SBA -

Measurements: Diameters 3.3, 3.75, 4.2, 5.0 mm with lengths 8, 10, 11.5, 13, 16 mm;

Conical Implant, Internal Hex, Pure & Porous, P&P -

Measurements: Diameters 3.3, 3.75, 4.2, 5.0 mm with lengths 8, 10, 11.5, 13, 16 mm;

Conical Implant, Internal Hex, SBA -

Measurements: Diameters 3.3, 3.75, 4.2, 5.0 mm with lengths 8, 10, 11.5, 13, 16 mm;

Dental Abutments:

Dental Abutments Internal Hex Connection: Locator Abutments, Angled Anatomic Abutments 15º, 25º, Angled Abutments 15º, 25º, Angled Multi Unit Abutments D-type 17º,30º (provided also as set), Temporary Sleeves for Multi Unit D-type, Straight Multi Unit Abutments D-type, Ball attachment abutments, Healing Caps (Narrow, Regular, Wide), Straight anatomic abutment, Straight abutments (Regular, Wide), Straight

abutment with shoulder(Regular, Wide), Snap on Transfer abutments, Straight Multi Unit Abutments D-type.

Dental Abutments Conical Connection: Healing Caps (Mini, Regular), Transfer Abutments (Mini, Regular), Transfer Abutment Regular, Straight Multi Unit Abutments C-type, Sleeves for Multi Unit C-type.

11 Indication for Use: :

UNIQA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments.

Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

12 Performance Standards or Special Controls :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- ISO 11137-1:2006 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

- ISO 11737-2: 2009 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ASTM F-1980 - 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-2:2009 Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.
- Chemical and SEM analysis performed on implants per Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.
- Endotoxin batch testing protocol per FDA Guidance Document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.

13 Substantial Equivalence :

Characteristic	Conical Implant, Pure & Porous, P&P Cat # UCI	MIS - SEVEN Implants	MIS V3 Conical Connection implants	OsseoSpeed TX S	A.B. Dental Implant system	DENTIN Dental Implant system
		Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device
510(k) number	K180598	K040807	K163349	K101732	K132125	K120530
Manufacturer	UNIQA Dental Ltd.	MIS Implants Technologies ltd	MIS Implants Technologies ltd	Astra Tech AB	A.B. Dental Device ltd	DENTIN Implants Technologies Ltd
Product Name	Conical Implant, Pure & Porous, P&P	SEVEN Implants	MIS V3 Conical Connection Dental Implant System	OsseoSpeed TX S	I5 Conical Implant	RAPID Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread	Tapered, Double Thread	Cylindrical tapered apex, threaded	Tapered, Double Thread	Tapered
Measurements: Ø / Length mm	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.75 Ø: 8 ,10, 11.5, 13,16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.3 Ø: 10, 11.5, 13, 16 4.3 Ø: 8 ,10, 11.5, 13, 16 4.9 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.0 Ø: 11, 13, 15 3.5 Ø: 8, 9, 11, 13, 15, 17 4.0 Ø: 6, 8, 9, 11, 13,15, 17 5.0 Ø: 9, 11, 13, 15, 17	3.5 Ø: 8 ,10, 11.5, 13, 16	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 7, 8 ,10, 11.5, 13 6.0 Ø: 7, 8 ,10, 11.5, 13
Connection Type	Internal conical connection, cone angulation 22º	Internal hex	Internal conical connection, cone angulation 12º	Internal conical connection, cone angulation 21º	Internal Hex	Internal Hex
Material	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium grade 4	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI
Surface Treatment	Clean&Porous, P&P (Hydroxyapatite and Calcium Phosphates)	Sand Blast and acid-etched	Sand Blast and acid-etched	TiO2-blasted fluoridemodified surface	Hydroxyapatite and Calcium Phosphates	Sand Blast & Acid Etched
Self tapping	Yes	Yes	Yes	Yes	Yes	Yes

Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The OsseoSpeed implants are intended to be used: • to replace missing teeth in single or multiple unit applications within the mandible or maxilla • for immediate placement in extraction sites and partially or completely healed alveolar ridge situations •for both one- and two stage surgical procedures • especially well in soft bone applications where implants with other implant surface treatments may be less effective • together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate • together with immediate loading protocol for single tooth restorations on implants 8 mm or longer • with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.	A.BDENTAL DEVICES® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. A.B. DENTAL DEVICES® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: I2,I5,I6BI. One Stage: I6, I6b, I6B. One Stage & One-Piece 3.0 mm diameter implants: I6, I6B, I6BI, are intended for	DENTIN® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage Implants: ONE PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.

Indication for Use					placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: I6, I6b, permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis. P14 Angulated Abutment Adapter is to be used with implant diameter 4.2mm and higher.	
Self tapping	✓	Gamma Ray	✓	✓	✓	✓
Sterilization	Gamma Ray	Double packaging	Gamma Ray	Gamma Ray	Gamma Ray	Gamma Ray
Packaging	Double packaging		Double packaging	Double packaging	Double packaging	Double packaging

Characteristic	Conical Implant, SBA Cat # UC7	MIS - SEVEN Implants	MIS V3 Conical Connection implants	OsseoSpeed TX S	DENTIN Dental Implant system
		Primary Predicate	Reference Device	Reference Device	Reference Device
510(k) number	K180598	K040807	K163349	K101732	K120530
Manufacturer	UNIQA Dental Ltd.	MIS Implants Technologies ltd	MIS Implants Technologies ltd	Astra Tech AB	DENTIN Implants Technologies Ltd
Product Name	Conical Implant, SBA	SEVEN Implants	MIS V3 Conical Connection Dental Implant System	OsseoSpeed TX S	RAPID Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread	Tapered, Double Thread	Cylindrical tapered apex, threaded	Tapered
Measurements: Ø / Length mm	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.75 Ø: 8 ,10, 11.5, 13,16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.3 Ø: 10, 11.5, 13, 16 4.3 Ø: 8 ,10, 11.5, 13, 16 4.9 Ø: 8 ,10, 11.5, 13, 16	3.0 Ø: 11, 13, 15 3.5 Ø: 8, 9, 11, 13, 15, 17 4.0 Ø: 6, 8, 9, 11, 13,15, 17 5.0 Ø: 9, 11, 13, 15, 17	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 7, 8 ,10, 11.5, 13 6.0 Ø: 7, 8 ,10, 11.5, 13
Connection Type	Internal conical connection, cone angulation 22º	Internal hex	Internal conical connection, cone angulation 12º	Internal conical connection, cone angulation 21º	Internal Hex
Material	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium grade 4	Titanium Alloy Ti6Al4V ELI
Surface Treatment	Sand Blast and acid-etched	Sand Blast and acid-etched	Sand Blast and acid-etched	TiO2-blasted fluoridemodified surface	Sand Blast & Acid Etched
Self tapping	Yes	Yes	Yes	Yes	Yes

Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The OsseoSpeed implants are intended to be used: • to replace missing teethin single or multiple unit applications within the mandible or maxilla • for immediate placement in extraction sites and partially or completely healed alveolar ridge situations •for both one- and two stage surgical procedures • especially well in soft bone applications where implants with other implant surface treatments may be less effective • together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate • together with immediate loading protocol for single tooth restorations on implants 8 mm or longer • with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.	DENTIN® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage Implants: ONE PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.

Self tapping	✓	✓	✓	✓	✓
Sterilization	Gamma Ray	Gamma Ray	Gamma Ray	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging	Double packaging	Double packaging	Double packaging

Characteristic	Conical Implant, Internal Hex, Pure & Porous, P&P Cat# USI	MIS - SEVEN Implants	A.B. Dental Devices Ltd	DENTIN Dental Implant system
		Primary Predicate	Reference Device	Reference Device
510(k) number	K180598	K040807	K132125	K120530
Manufacturer	UNIQA Dental Ltd.	MIS Implants Technologies ltd	A.B. Dental Device ltd	DENTIN Implants Technologies Ltd
Product Name	Conical Implant, Internal Hex, Pure & Porous, P&P	SEVEN Implants	I5 Conical Implant	RAPID Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread	Tapered, Double Thread	Tapered
Measurements: Ø / Length mm	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.75 Ø: 8 ,10, 11.5, 13,16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.5 Ø: 8 ,10, 11.5, 13, 16	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 7, 8 ,10, 11.5, 13 6.0 Ø: 7, 8 ,10, 11.5, 13
Connection Type	Internal hex	Internal hex	Internal Hex	Internal Hex
Material	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI
Surface Treatment	Clean&Porous, P&P (Hydroxyapatite and Calcium) Phosphates)	Sand Blast and acid-etched	Hydroxyapatite and Calcium Phosphates	Sand Blast & Acid Etched
Self tapping	Yes	Yes	Yes	Yes

Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	A.BDENTAL DEVICES® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. A.B. DENTAL DEVICES® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: I2,I5,I6BI. One Stage: I6, I6b, I6B. One Stage & One-Piece 3.0 mm diameter implants: I6, I6B, I6BI, are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: I6, I6b, permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis. P14 Angulated Abutment Adapter is to be used with implant diameter 4.2mm and higher.	DENTIN® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage Implants: ONE PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants
Self tapping	✓	✓	✓	✓
Sterilization	Gamma Ray	Gamma Ray	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging	Double packaging	Double packaging

Characteristic	Conical Implant, Internal Hex, SBA Cat# US7	MIS - SEVEN Implants	DENTIN Dental Implant system
		Primary Predicate	Reference Device
510(k) number	K180598	K040807	K120530
Manufacturer	UNIQA Dental Ltd.	MIS Implants Technologies ltd	DENTIN Implants Technologies Ltd
Product Name	Conical Implant, Internal Hex, SBA	SEVEN Implants	RAPID Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread	Tapered
Measurements: Ø / Length mm	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.75 Ø: 8 ,10, 11.5, 13,16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 8 ,10, 11.5, 13, 16	3.3 Ø: 8 ,10, 11.5, 13, 16 3.75 Ø: 8 ,10, 11.5, 13, 16 4.2 Ø: 8 ,10, 11.5, 13, 16 5.0 Ø: 7, 8 ,10, 11.5, 13 6.0 Ø: 7, 8 ,10, 11.5, 13
Connection Type	Internal hex	Internal hex	Internal Hex
Material	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI
Surface Treatment	Sand Blast and acid-etched	Sand Blast and acid-etched	Sand Blast & Acid Etched
Self tapping	Yes	Yes	Yes

Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	DENTIN® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage Implants: ONE PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.
Self tapping	✓	✓	✓
Sterilization	Gamma Ray	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging	Double packaging

UNiQA DENTAL

Dental Abutments

	UNIQA Dental Abutments	
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
Product Name	***Locator Abutments # ULAR***	***Locator Abutments***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.
Dimensions mm	Height 1, 2, 3, 4, 5	Height 0,1,2,3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Related accessories	Silicon caps (Cat#ULCR)- soft, standard, strong; Metal cap(Cat#ULMR);	Silicon caps: soft, standard, strong; Metal cap (MM-LFA50)
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
Product Name	**Angled Anatomic Abutments# *UAAR***	***Esthetic Angulated Abutment***

Dimensions mm	Height 1,2,3,4 - Angle 15 Height 1,2,3,4 - Angle 25	Height 1,2,3 - Angle 15 Height 1,2,3 - Angle 25
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Company / 510k	***UNIQA Dental ltd #UABR***	***MIS K040807***
		Primary Predicate
Product Name	***Angled Abutment***	***Angulated Cement Abutment***
Dimensions mm	Length 9,12 - Angle 15, 25	Length 9,11 - Angle 15, 25
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***Nobel Biocare K072570***
		Primary Predicate	Reference device
Product Name	**Angled Multi Unit Abutment, MUA, D-type #UAMD**	***Esthetic Angulated Abutment***	***Multi-Unit Abutment***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

	prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.		
Dimensions	Height 1,2,3 - Angle 17 Height 1,2,3 - Angle 30	Height 1,2,3 - Angle 15 Height 1,2,3 - Angle 25	*Height 1.5, 2.5, 3.5, 4.5* *Angles 17, 30*
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex/Conical
Related Components	Sleeve for Multi Unit Abutment, MUA, Temporary, D-type#USTD Sleeve for Multi Unit Abutment, MUA, Temporary, V-type#USTV + screw (#UMSD)		Sleeve=Temporary copying (29046) + screw, plastic cap, MU screw#29285 Related tools are applicable

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***MIS K163349***
		Primary Predicate	Reference device
Product Name	**Straight Multi Unit Abutment, MUA, D-type # USMD**	***Anatomic transgingival Abutment***	**Straight Multi Unit Abutments**
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary

	indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.		lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.
Dimensions mm	Diameter: Regular Heights 1,2,3,4	Height 1,2,3,4	Diameter: Regular Heights 1,2,3,4,5
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Conical Hex
Related Components	Sleeve, Healing Cap, plastic cap		Sleeve, Healing Cap, plastic cap
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***Nobel Biocare K072570***
		Primary Predicate	Reference device
Product Name	**Set Angeled Multi Unit Abutment, MUA, D-type, Castable Sleeve # UAMC**	***Esthetic Angulated Abutment***	***Multi-Unit Abutment***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

	with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.		
Dimensions mm	Diameter: Regular Height 1,2,3 - Angle 17 Height 1,2,3 - Angle 30	Height 1,2,3 - Angle 15 Height 1,2,3 - Angle 25	*Height 1.5, 2.5, 3.5, 4.5* *Angles 17, 30*
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex/Conical
Related Components	The set is available with a Plastic sleeve + Sleeve screw + instrument + Multi unit screw (#UMSD)		Sleeve=Temporary copying (29046) + screw, plastic cap, MU screw#29285 Related tools are applicable
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	**Nobel Biocare K072570**
		Primary Predicate	Reference device
Product Name	**Set Angeled Multi Unit Abutment, MUA, D-type, Temporary Sleeve # UAMT**	***Esthetic Angulated Abutment***	**Multi-Unit Abutment**
Dimensions mm	Diameter: Regular Height 1,2,3 - Angle 17 Height 1,2,3 - Angle 30	Height 1,2,3 - Angle 15 Height 1,2,3 - Angle 25	Height 1.5, 2.5, 3.5, 4.5 Angles 17, 30
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex/Conical
Related Components	The set is available with a Transfer sleeve + Sleeve screw + instrument + Multi unit screw (#UMSD)		Sleeve=Temporary copying (29046) + screw, plastic cap, MU screw#29285

			Related tools are applicable
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	**Nobel Biocare K072570**
		Primary Predicate	Reference device
Product Name	***Healing cap for MUA, D-type #UMHD***	***Healing Caps***	**Multi-Unit Abutment / Healing cap#31145**
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
Dimensions mm	Height 4.0	Wide - Diameter. 5.0, 6.5; Height 3,4,5,6 Narrow - Diameter 3.3, 4.3 - Height 2, 3, 4, 6,8	Heights 4.1, 5.5

		Standard - Diameter 4.0, 4.8, 5.5; Height 2,3,4,5,6	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
Product Name	***Ball Attachment #UBAR***	***Ball Attachment***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.
Dimensions mm	Height 0.5,1,2,3,4,5,6, 7	Height 1,2,3,4,5
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Related Components	Metal Caps(#UBMR-0001), Silicon Caps(#UBSR-0001)	Metal Caps, Silicon Caps

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
Product Name	***Healing Caps #UHXX***	***Healing Caps***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.
Dimensions mm	Wide (# UHCW) - Diameter 5.5, 6.3 Height 2,3,4,5,6,7 Narrow (# UHCN) - Diameter 3.5; Height 3, 5,7 Regular (#UHCR) - Diameter 4.6, Height 2,3,4,5,6,7	Wide - Diameter. 5.0, 6.5; Height 3,4,5,6 Narrow - Diameter 3.3, 4.3 - Height 2, 3, 4, 6,8 Standard - Diameter 4.0, 4.8, 5.5; Height 2,3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate

Product Name	**Straight *Anatomic Abutment* # USAR**	***Anatomic transgingival Abutment***
Dimensions mm	Height 1,2,3,4	Height 1,2,3,4
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***A.B.Dental Devices Ltd K112440***
		Primary Predicate	Reference device
Product Name	***Straight Abutment #USBX***	***Cemented Abutment***	***P3 Abutment Anti rotation***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	The AB Dental Devices implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. 17 Integral implant, 15 Conical implant, P15 Temporary abutment, P12-T,L Temporary flat connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Dimensions mm	Diameter : Regular (#USBR)	Diameter : Regular, Wide	Diameter : 3.0, 3.75, 5

	Length 5, 7, 9, 11, 13, 15 mm Diameter : Wide (# USBW) Length 5, 7, 9, 11, 13, 15 mm	Length 5, 7, 9, 12 mm (=Heights 1,2,3,4)	Length 5, 7, 9, 11, 12, 15
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
Product Name	***Straight Abutment* with shoulder #USSX**	***Cemented Abutment***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.
Dimensions mm	Diameter : Heights 1,2,3,4	Diameter : Regular, Wide Heights 1,2,3,4
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
	Snap on transfer #UTSR	***Cemented Abutment***
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.
	Diameter : Regular, Heights 1,2,3,4,5	Diameter : Regular, Slim, Wide Heights 1,2,3,4
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI. or gold
Connection	Internal Hex	Internal Hex
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***
		Primary Predicate
Product Name	***Screw for Abutment #USXX***	***Ti Base***
Dimensions mm	Measurements: Length 8.3 mm #USWR Length 8.1 mm #USWL	Diameter: Narrow, Regular, wide Length 8.1 mm
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.

Connection	Internal Hex	Internal Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***MIS K163349***
		Primary Predicate	Reference device
Product Name	**Straight Multi Unit Abutment, MUA, V-type# USMV**	***Esthetic Angulated Abutment***	**Straight Multi Unit Abutments**
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.
Dimensions mm	Diameter: Regular Heights 1,2,3,4	Height 1,2,3 - Angle 15 Height 1,2,3 - Angle 25	Diameter: Regular Heights 1,2,3,4,5

Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Conical Hex
Related components *(L=length)*	Screw for Multi Unit Abutment sleeve, V-type (#UMSV-0002) - measurement 3.9 L mm ; Healing cap for Multi Unit Abutment, MUA, V-type (#UMHV-0004) - 3.1 L mm		Multi unit screw measurement 3.8 L mm; Healing Cap measurement 4.3 L mm
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***MIS K163349***
		Primary Predicate	Reference device
Product Name	**Healing Cap # UOHX**	***Healing Caps***	**Healing Cap**
Dimensions mm	Diameter: Mini (#UOHM) - Diameter 4.0, 4.5 Heights 3, 4, 5,7 Regular (#UOHR) - Diameter 4.0, 4.5, 5.0, 6.0, 7.0 Heights 3, 4, 5, 7	Wide - Diameter. 5.0, 6.5; Height 3,4,5,6 Narrow - Diameter 3.3, 4.3 - Height 2, 3, 4, 6,8 Standard - Diameter 4.0, 4.8, 5.5; Height 2,3,4,5,6	Diameter: Slim Diameter 3.3, 4.0, 4.8, Heights 3,4,5,6,8 Regular, Diameter 3.9, 4.3, 5.0, Heights 3,4,5,6,8
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Conical Hex	Internal Hex	Conical Hex
Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***MIS K163349***
		Primary Predicate	Reference device
Product Name	**Transfer Abutment #UOTX**	***Cemented Abutment***	**Cementing Abutment**
Dimensions mm	Mini Diameter: 4.5 mm, Height 1, 2, 3, 4, 5 mm Lengths: 5.5, 7 mm (#UOTM) Regular Diameter: 4.5, 5.0, 6.0 mm, Height 1, 2, 3, 4, 5 mm, Lengths: 4.0(not for 4.5), 5.5, 7 mm(#UOTR) Provided with: Screw Mini Conical (#UOSM-0001) Screw Regular Conical (#UOSR-0001	Diameter : Regular, Wide Heights 1,2,3,4	Narrow Diameter: 4.0 Length 1, 3 Narrow Diameter: 4.8 Length 1,2, 3 Standard Diameter: 4.8 Length 1,2,3,4 Height 4,6,8. Provided with: Screw MN-S0160 (mini) MD-S0200, MD-S0222 (standard)
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.

Connection	Conical Hex	Internal Hex	Conical Hex

Company / 510k	***UNIQA Dental ltd K180598***	***MIS K040807***	***MIS K163349***
		Primary Predicate	Reference device
Product Name	**Straight Multi Unit Abutment, MUA, C-type (#UOMX)**	***Anatomic transgingival Abutment***	**Multi Unit**
Indication for Use	UNIQA Dental ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. UNIQA Dental ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. UNIQA Conical Connection Implants: #UCI & #UC7 are to be used only with straight abutments. Conical Mini implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	The MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.
Dimensions mm	Mini Diameter: 4.0 Height 1, 2,3,4 (#UOMM)	Height 1,2,3,4	Narrow Diameter: Heights 1,2,3,5 Standard Diameter: Heights 1,2,3,4,

	Regular Diameter: 4.0, 5.0, 6.0 Height 1, 2,3,4,5 (5mm not for 4Ø) (#UOMR)		5 (also available Angulated 17, 30 with height 1,2)
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Conical Hex	Internal Hex	Conical Hex
Related Components	Sleeve for Multi Unit Abutment, MUA, Rotation, C-type (#USTC-Rx) Diameter Regular : 4.0, 5.0, 6.0 Length: 7. Sleeve for Multi Unit Abutment, MUA, Fixed, C-type (#USTC-Fx) Diameter Regular : 4.0, 5.0, 6.0 Length: 7. Screw for MUA sleeve, C-type (#UMSC-0002)		Temporary cylinder (#MU-TO480) Screw (#MU-S0220)

14 Summary of Equivalence:

UNIQA® Dental Implants System share the same indication for use with its Primary Predicate MIS SEVEN Implant K040807; with two differences UNIQA Conical Implants (#UCI and #UC7) are to be used only with straight abutments, and that the Conical Mini implants (Ø3.3mm) indications are similar to the Reference Device MIS V3 Conical Connection Dental Implant System K163349 the Narrow Implants. The differences do not raise different safety or effectiveness issues as verified by Fatigue testing per ISO 14801:2007.

UNIQA® Dental Implants System, line of Conical Connection Implants (#UCI and #UC7) share similarity with its Reference Device MIS V3 Conical Connection Dental Implant System K163349 and its Reference Device Astra Tech OsseoSpeed TX K101732 in terms of intended use, technological characteristics, conical connection, sterilization method, surgical procedure. The differences are as follow: UNIQA Conical Implants are available in two options of surface treatment (1) SBA - Sand Blast with acid etched in similar to its Reference Device MIS K163349; and (2) Pure & Porous, P&P which is similar to its Reference Device A.B.DENTAL DEVICES LTD K132125; UNIQA line of Conical Hex Implants 3.3Ø are also provided with 8 mm length, whereas with its Reference Device MIS K163349 3.3Ø implants are provided only from 10 mm length. However, UNIQA share similar implant measurement 3.3Øx8 mm length with its other Reference Device DENTIN K120530; UNIQA conical connection cone angulation is 22º whereas with its Reference Device MIS K163349 introduces 12º, and its other Reference Device OsseoSpeed TX K101732 introduces 21º; The cone angulation is very similar to the OsseoSpeed TX K101732 with a minor difference; UNIQA conical connection implants currently are not distributed with angled abutments thus raise no new and/or different risks. UNIQA implant diameter range is slightly different (3.3, 3.75, 4.2, 5.0) but still is within the range of the Reference Device (3.3, 4.9, 4.3, 5.0); The differences do not raise different safety or effectiveness issues as verified by Fatigue testing per ISO 14801:2007.

UNIQA® Dental Implants System, line of Conical Implant Internal Hex (#USI and #US7) share similarity with its Primary Predicate MIS SEVEN Implant K040807 in terms of intended use, technological characteristics, conical body design, internal hex connection, sterilization method, surgical procedure. The differences are as follow: UNIQA Conical

Implants Internal Hex are available in two options of surface treatment (1) SBA - Sand Blast with acid etched in similar to its Primary Predicate MIS K040807; and (2) Pure & Porous, P&P which is similar to its Reference Device A.B.DENTAL DEVICES LTD K132125; UNIQA line of Conical Implant Internal Hex is available in 3.3Ø, whereas with its Primary Predicate MIS K040807 is available from 3.5Ø. However, this difference doesn't raise any new risk since the same measurements are exist in the Reference Device K120530;

15 Performance Testing:

Clinical Testing - No clinical data is included in this submission.

Sterilization Validation Test was carried out with accordance to ISO 11137 in order to ensure safety and effectiveness related to UNIQA® Dental Implants - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Shelf Life Test was carried out with accordance to ASTM F-1980 in order to validate the claimed shelf life of 5 years.

Steam Sterilization Test was carried out with accordance to ISO 17665 in order to ensure safety and effectiveness related to UNIQA® Dental Abutments - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Biocompatibility - UNIQA Dental Implants are made of Ti6Al4V ELI using the conventional manufacturing process. Cytotoxicity testing was carried out with accordance to ISO 10993-5 in order to demonstrate that the manufacturing process did not change the biocompatibility profile. No additional biocompatibility testing was deemed necessary since the devices are constructed from medical quality raw material which conforms the international standard ASTM F-136 Eli used for human implant applications.

Fatigue test was carried out with accordance to ISO 14801 in order to verify the mechanical connection strength of implant/abutment, results have demonstrated the performance with the use of UNIQA® Dental Implants / Abutments.

Surface Test was carried out to ensure the cleanness of the implant surface, surface results were met UNIQA requirements.

Risk Assessment was carried out with accordance to ISO 14971 and has demonstrated no new safety and/or effectiveness issues.

16 Conclusion:

As verified by substantial equivalence, risk assessment and bench testing UNIQA® Dental Implants System shares similarity to its predicated devices in terms of intended use, indication for use, raw material, technological characteristics and performance. Therefore, UNIQA® Dental Implants system is considered to be substantially equivalent to its predicate devices.