Uniqa Dental, Ltd.
% Daniela Levy
Regulatory & Quality Consultant
Sterling Medical Registration
22750 Califa Street
Woodland Hills, California 91367

June 25, 2026

Re: K251188
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 27, 2026
Received: May 28, 2026

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251188

Device Name

UNIQA® Dental Implants System

Indications for Use *(Describe)*

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.
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 C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

UNIQADENTAL

Section 4 - 510(k) Summary (21 CFR 807.92)

510(k) Number K251188

1 Type of Submission Premarket Notification (21 CFR 807.90(e)) 510(k) Traditional

2 Submission Owner
UNIQA DENTAL LTD.
Dima Goberman - CEO
2 Ha-Tsoran street
Netanya 4250602
Israel

3 Official Correspondent
Sterling Medical Registration
Contact Person
Daniela Levy - Regulatory & Quality Consultant
22750 Califa Street
Woodland Hills, CA 91367
Phone: 1-213-787-3027
Email: sterlingmedical2017@gmail.com
www.Sterlingmedicalregistration.com

4 Submission Date June 24, 2026

5 Device Trade Name UNIQA® Dental Implants System

6 Regulation Description Endosseous Dental Implants Abutment

7 Classification
Product Code Primary : DZE
Device Name : Implant, endosseous, root-form
Regulation No : 872.3640
Class : II
Panel : Dental
Product Code Secondary : NHA
Name : Abutment, implant, dental, endosseous
Class : II
Panel : Dental

8 Identification of Legally Marketed Predicate Devices :

Primary Predicate:

UNIQA® Dental Implants System K180598, UNIQA Dental Ltd

Reference Predicate for Implants:

NobelActive® K142260, Nobel Biocare AB

Reference Predicates for Abutments:

MIS® Dental Implant System K040807, MIS Implant Technologies Ltd

MIS® V3 Conical Connection Dental Implant K163349, MIS Implant Technologies Ltd

MIS® Internal Hex Dental Implant System K180282, MIS Implant Technologies Ltd

NobelActive® Multi Unit Abutment K072570, Nobel Biocare AB;

SGS® Dental Implant System K182219, SGS® International Ltd

ZEST LOCATOR® Angled Abutment K252944, Zest Anchors, LLC

9 Device Description: :

The UNIQA® Dental Implant System, as cleared for marketing under 510K K180598, consists of Internal Hex Dental Implants, Conical Connection Dental Implants, Healing Caps, Dental Abutments and Superstructures. UNIQA® Dental Implants and Abutments are made of titanium alloy Ti6AL4V Eli.

This submission introduces a minor design improvement to the external implant body of the approved K180598 Dental Implants – Internal Hex & Conical Connection, featuring a slight tapering for an enhanced design.

UNIQA® Dental Implants are available in two options of surface treatment (1) Pure & Porous, P&P - which consists of Hydroxyapatite and Calcium Phosphates sand blast large particles following acid etched ; or (2) SBA - which consists of sand blast large particles with acid etched:

Conical Hex Connection Dental Implants with the following measurements:

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

Internal Hex Dental Implants with the following measurements:

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

Additionally, this submission introduces range of dental abutments compatible with UNIQA® Dental Implant System. Abutment screws are included in the abutment packaging but are also available separately.

- **Healing caps** consist of titanium alloy, CNC machined, introducing the following platforms and measurements:

For internal hex:

RP - Ø4 Gingival Height 3mm

WP Ø 6.3, 7 - Gingival Height 2,3,4,5,6,7mm

WP Ø7 - Gingival Height 2,3,4,5,6,7mm

For conical connection:

MP Ø4 - Gingival Height - 3,4,5,7mm; Ø4.5 Gingival Height - 2,3,4,5 ,6 ,7mm;

RP Ø4 - Gingival Height - 3,5,7mm; Ø4.5, Ø5, Ø6, Ø7 Gingival Height - 2,3,4,5, 6, 7mm

- **DLOC Attachments** are intended for overdenture restoration. Consist of titanium alloy, CNC machined with or without coloring anodize. Available straight and angulated at 9°, 15°, 30°, introducing the following platforms and measurements for internal hex / conical connection:

Straight - RP, WP - Gingival Height 1, 2, 3, 4, 5, 6, 7mm

Straight - MP - Gingival Height 1, 2, 3, 4, 5, 6mm

RP Angle 9°, 15°, 30° - Gingival Height 1,2,3mm

MP Angle 9°, 15° - Gingival Height 1,2,3mm

Related silicon, metal caps are available.

- **Ball Attachments** are intended for overdenture restoration. Consist of titanium alloy, CNC machined with or without coloring anodize. Available straight and angulated at 9°, 15°, 30°, introducing the following platforms and measurements for internal hex / conical connection:

Straight - RP, Gingival Height 0.5,1,2,3,4,5,6,7mm

Straight - MP - Gingival Height 0.5, 1,2,3,4,5,6 mm

RP Angle 9°, 15°, 30° - Gingival Height 1,2,3mm

MP Angle 9°, 15° - Gingival Height 1,2,3mm

Related silicon, metal caps are available.

- **Straight Abutments with Shoulder** are intended for cement restoration, consist of titanium alloy, CNC machined, introducing the following platforms and measurements for internal hex:

RP Gingival Height 5mm

RP Ø6 Gingival Height 1,2,3,4,5mm

- **Straight Abutments** are intended for cement restoration, consist of titanium alloy, CNC machined, introducing the following platforms and measurements for internal hex/conical connection:

RP Ø4.5, 5,6,7 Gingival Height 1,2,3,4,5mm

MP Ø4.5 Gingival Height 1,2,3,4,5mm

- Angled **15° / 25°Abutments** are intended for cement restoration, consist of titanium alloy, CNC machined, introducing the following platforms and measurements for conical connection:

RP - Angle 15°, 25° - Gingival Height 1,2,3,4mm

MP - Angle 15°, 25° - Gingival Height 1,2,3mm

- **Straight Multi-Unit Abutments D- Type** are intended for screw restoration, consist of titanium alloy, CNC machined, machined with or without coloring anodize, introducing the following platforms and measurements for internal hex/conical connection:

RP - Gingival Height 1,2,3,4,5mm

MP - Gingival Height 1,2,3,4,5mm

Included related components healing caps, temporary sleeves.

- **17°/30° Angled Multi-Unit Abutments D-Type** are intended for screw restoration, consist of titanium alloy, CNC machined, machined with or without coloring anodize, introducing the following platforms and measurements for internal hex/conical connection:

RP - Angle 15°, 30° - Gingival Height 1,2,3,4mm

MP - Angle 15°, 30° - Gingival Height 1,2,3,4mm

Included related components healing caps, temporary sleeves.

- **Straight Multi-Unit Abutments V-Type** are intended for screw restoration, consist of titanium alloy, CNC machined, machined with or without coloring anodize, introducing the following platforms and measurements for internal hex/conical connection:

RP - Gingival Heights 0.5,1,2,3,4,5, 6mm

MP - Gingival Heights 0.5,1,2,3,4,5mm

Included related components healing caps, temporary sleeves.

- **Temporary Sleeves for Multi-Unit Abutments** are intended to be for used with UNIQA's Multi Units abutments. Consist of titanium alloy, CNC machined, machined with or without coloring anodize, introducing the following platforms and measurements for internal hex/conical connection:

Gingival Height - 1.5,3,4,6,8,12mm for V-type

10 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.

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.

11 Substantial Equivalence :

Dental Implants

Table No.1	Subject Device	Primary Device	Reference Device		
Technical Characteristic	**UNIQA Implant Conical =** UV11/UV11s Implant & **UNIQA Internal Hex =** UH8/UH8s Implant	**Conical Implant, Pure&Porous, P&P / SBA Conical Implant, Internal Hex, Pure&Porous, P&P / SBA**	**Nobel Active**		SE Discussion
FDA 510(k) No.	K251188	K180598	K142260		
Manufacturer	UNIQA Dental Ltd.	UNIQA Dental Ltd.	Nobel Biocare AG		
Device design DZE	Endosseous Dental Implant	Endosseous Dental Implant	Endosseous Dental Implant		No Differences
Product Image					Subject Device implant design is the same as Primary device having more tapered body contour in similar to the reference device.
Connection Type	Internal Hex, and Conical Connection, cone angulation 11° (22°)	Internal Hex, and Conical Connection, cone angulation 11° (22°)	Internal conical connection, cone angulation 12° (24°)		No Differences From primary device
Thread Design	Tapered, Double Thread	Tapered, Double Thread	Tapered, Double Thread		No Differences
Length mm	UNIQA Dental Implants (Internal Hex & Conical Connection) are cleared by K180598 – this submission introduces a minor design change to the implant body contour, making it more tapered. 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	3.3 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	3.5 Ø: 8.5 ,10, 11.5, 13, 15, 18 4.3 Ø: 8.5 ,10, 11.5, 13, 15, 18 5.0 Ø: 8.5 ,10, 11.5, 13, 15, 18 5.5 Ø: 7, 8.5 ,10, 11.5, 13, 15		From primary device, the new minor change of more tapered design is similar to the reference device.
Material	Titanium Alloy Ti6Al4V ELI	Titanium Alloy Ti6Al4V ELI	Titanium grade CP4		No Difference Subject device is identical to Primary Device
Surface Treatment	(a) Pure&Porous- Hydroxyapatite & Calcium sand blast large particles following acid etched or (b) SBA –Aluminum Oxide Al203 sand	(a) Pure&Porous- Hydroxyapatite & Calcium sand blast large particles following acid etched or	TiUnite / TiUltra		No Difference Subject device is identical to Primary Device.

	blast large particles following acid-etched	(b) SBA –Aluminum Oxide Al203 sand blast large particles following acid-etched			
Operation	Surgical Implantation Procedure, Conventional Dental Drill Protocol	Surgical Implantation Procedure, Conventional Dental Drill Protocol	Surgical Implantation Procedure, Conventional Dental Drill Protocol		No Differences Subject device is identical to Primary Device.
Sterilization	Gamma Irradiation, Single Use	Gamma Irradiation, Single Use	Gamma Irradiation, Single Use		No Differences Subject device is identical to Primary Device.
Packaging	Double packaging	Double packaging	Double packaging		No Differences Subject device is identical to Primary Device.
Used under similar conditions of use	Fully or partially edentulous patients	Fully or partially edentulous patients	Fully or partially edentulous patients		No Differences Subject device is identical to Primary Device.
Population	Adults	Adults	Adults		No Differences Subject device is identical to Primary Device.
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. 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	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. 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	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.		No Differences Subject devices are identical to Primary Device.

	must be splinted if using two or more narrow implants adjacent to one another.	central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.			

Indication for Use

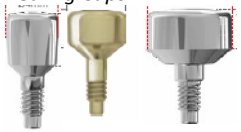
Table 1. SE Indication for Use	Primary Device	Reference Device	Reference Device	
UNIQA Dental Implants System **Abutments System**	**UNIQA Dental Implants System** **Abutments System**	**MIS V3 Conical Connection implants** **Abutments System**	**MIS Dental Implants System** **Abutments System**	SE Discussion
K251188	K180598	K163349	K040807	N/A
UNIQA Dental Ltd.	UNIQA Dental Ltd.	MIS Implants Technologies ltd	MIS Implants Technologies ltd	N/A
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. 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	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. 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	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 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.	No Differences Subject Devices -additional measurements and abutments are identical to Primary Device UNIQA K180598 or similar to the References Devices – MIS K163349, K040807. UNIQA Indication for use are the same as the Primary Device K180598. The Subject Device

or more narrow implants adjacent to one another.	or more narrow implants adjacent to one another.			

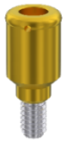
Reference Device Angular Ball Attachment	Reference Device Locator Angled Abutment	Reference Device Angular Ball Attachments	Reference Device ***NobelActive Multi Unit Abutment***	SE Discussion
K180282	K252944	K182219	K072570	Subject Device UNIQA'S angular Ball attachments share similar indications as the Reference Devices SGS K182219 and MIS K180282. Subject Device UNIQA'S angular DLOC abutments share similar indications as the Reference Devices SGS K182219 and Zest K252944; The Subject Device UNIQA Multi Unit Abutment is the same as the Primary Device UNIQA K180598, just introducing new profile height 4mm which is in similar to the Reference Device Nobel Multi Unit K072570.
MIS Internal Hex Dental Implant System	ZEST LOCATOR® Angled Abutment, Zest Anchors, LLC	SGS International ltd	Nobel Biocare AB	
MIS dental implant systems are 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 & UNO) 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. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable restorations retained by endosseous implants to restore masticatory function for the patient.	SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. Narrow diameter implants (3.2) are intended for maxillary lateral incisors and mandibular lateral and central incisors. Two Stage Implants: P7N, P1D, P5D, P7D. PEEK Temporary Abutments are not to exceed 30 days.	The NobelActiveMulti-unit Abutment a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	

Dental Abutments

1.1. Table No.2	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***UNIQA Healing Caps***	***UNIQA Healing Caps***	***MIS Healing Caps***	***SE Discussion***

Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	MIS Implant Technologies Ltd	
510k	K251188	K180598	K163349, K040807	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	*Healing Caps* 	*Healing Caps* 	*Healing Caps* 	No differences
Dimensions mm *Gingival Height=GH* *Length=L* *Diameter= Ø*	Internal: Standard - Ø4 GH3 Wide Ø 6.3, 7 - GH 2,3,4,5,6,7 Wide Ø7 - GH 2,3,4,5,6,7 Conical: MP Ø4– GH-3,4,5,7; Ø4.5– GH-2,3,4,5 ,6 ,7 RP Ø 4-GH-3,5,7 RP- Ø 4.5,5,6,7 GH-2,3,4,5, 6, 7	Internal: Slim, NP - GH 2,3,4,5,6,7 Standard Ø4,4.5- GH- 2,3,4,5,6,7 Wide Ø5.5 - GH- 2,3,4,5,6,7 Narrow Ø4- GH- 5,7 Conical mini - Ø4,4.5,– GH-3,4,5 Conical – Ø4,4.5,5,6,7 – GH-3,4,5	Internal: NP 4.0,4.3ø, GH-2,3,4,5,6,8mm RP 4.0,4.8,5.5ø, GH-3,4,5,6mm WP 5.0,5.5,6.5ø, GH-3,4,5,6mm Conical: NP 3.3,4.0,4.8ø, GH-2,3,4,5,6,8mm RP 3.9,4.8,5.8ø, GH-2,3,4,5,6,7,8mm WP 5.5,6.3ø, GH-2,3,4,5mm	No differences Subject Device is in the limits of Primary Device and/or Reference Device.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined	CNC Machined	CNC Machined with or without coloring anodize	No differences from Subject Device.
Connection	Internal Hex Conical Connection	Internal Hex Conical Connection	Internal Hex Conical Connection	No differences
Operation	Screw Retained	Screw Retained	Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Provided Sterile, Single Use (IFU MPUI101)	Subject Device is the same as Primary Device

1.2. Table No.3	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***DLOC attachment abutment***	***Locator Abutments***	***MIS - LOCKiT Abutments***	***SE Discussion***

Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	MIS Implant Technologies Ltd	
510k	K251188	K180598	K163349, K040807	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	*DLOC attachment abutment* 	*Locator Abutments* 	*LOCKiT Abutments* 	No differences
Dimensions mm *Gingival Height=GH* *Length=L* *Diameter= Ø*	GH 1, 2, 3, 4, 5, 6, 7 RP,WP MP GH 1, 2, 3, 4, 5, 6	GH 1, 2, 3, 4, 5 RP,WP	GH 0,1,2,3,4,5,6 NP, SP, WP	Subject Device is the same as Primary Device Added heights: 6mm is within the limits of the Reference Device. An additional 7mm is not within the limits but is very similar. It is considered a minor difference with no effect since UNIQAs' abutments line includes 7mm height in other UNIQA K180598 abutments designs such as Healing caps 2-7mm, ball attachment 0.5-7mm.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	No differences from Primary Device.
Connection	Internal Hex Conical Connection	Internal Hex Conical Connection	Internal Hex Conical Connection	No differences
Related Components	Silicon caps soft, standard, strong, housing cap – for all overdenture restoration. Added:  Silicon Cap soft	 Silicon caps soft, standard, strong, housing cap – for all overdenture restoration	Silicon Caps range and metal housing 	No differences
Operation	Overdenture Screw Retained	Overdenture Screw Retained	Overdenture Screw Retained	No differences
Sterilization	Non Sterile, Single Use	Non Sterile, Single Use	Non Sterile, Single Use	No differences

	Steam sterilization	Steam sterilization	Steam sterilization	

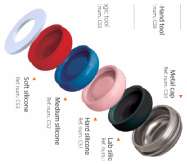
1.3. **Table No.4**	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***DLOC attachment, angular***	***S35-S7 - S-lock Angular Abutment***	***ZEST Locator Angeled Abutment***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	SGS International Ltd	Zest Anchors, LLC	
510k	K251188	K182219	K252944	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	*DLOC Attachment, angular* 	S35-S7 - S-lock Angular Abutment  S5-S7 - Easy-Fix Angular Abutment 	*Locator Angeled Abutment* 	Subject Device has a similar design to the primary device and reference device. (Note: In the Zest locator image the screw is not shown, but basically the Subject Device and the Reference Devices share similar design, clinical use and technological characteristics)
Dimensions mm *Gingival Height=GH*	RP Angle 9°, 15°, 30° GH 1,2,3 MP Angle 9°, 15° GH 1,2,3	GH 1,2,3 - Angle 17 GH 1,2,3 - Angle 30 RP	GH 2.5 - 7.5 mm - Angle 15 NP, RP, WP	Subject Device has a slight difference vs Primary Device and the Reference Device since only Subject Device has 9°, this raises no significant difference, since this small angle is covered by the worse scenario of the 30° angle.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No Differences
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with TiN	No Differences from primary device
Connection	Internal Hex Conical Connection	Internal Hex	Internal Hex Conical Connection	No differences
Related Components	Silicon caps soft, standard, strong, housing cap – for all overdenture restoration. Added:  Silicon Cap soft		Silicon caps and metal 	No Differences

		Silicon caps soft, standard, strong, housing cap – for all overdenture restoration		
Operation	Overdenture Screw Retained	Overdenture Screw Retained	Overdenture Screw Retained	No Differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences

1.4. **Table No.5**	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***Ball Attachment***	***Ball Attachment***	***Ball Attachment***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	MIS Implant Technologies Ltd	
510k	K251188	K180598	K163349, K040807	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	*Ball Attachment* 	*Ball Attachment* 	*Ball Attachment* 	No differences
Dimensions mm *Gingival Height=GH*	RP GH- 0.5,1,2,3,4,5,6, 7 MP - GH 0.5, 1,2,3,4,5,6	RP GH 0.5,1,2,3,4,5,6, 7	GH 1,2,3,4,5 NP,SP,WP 4/0,4.4,5.0	Subject Device is the same as Primary Device.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	No differences
Connection	Internal Hex Conical Connection	Internal Hex	Internal Hex Conical Connection	No differences
Related Components	 Silicon Cap soft, ExtraSoft:	 Metal Cap/housing, Silicon Cap soft, standard, Strong:	Metal Caps, Silicon Caps	No Differences

				
Operation	Overdenture Screw Retained	Overdenture Screw Retained	Overdenture Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences

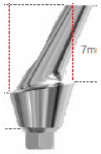
1.5. **Table No.6**	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***Ball Attachment, angular***	***Angular Ball Attachment***	***Angulated ball attachment anchor***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	SGS International Ltd	MIS Implant Technologies Ltd	
510k	K251188	K182219	K180282	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	*Ball Attachment, angular* 	S3-S7 - Angular Ball Attachment 	*Angulated ball attachment anchor* 	The Subject Device features a ball attachment with angulation similar to both primary and reference device.
Dimensions mm *Gingival Height=GH*	RP Angle 9°, 15°, 30° GH 1,2,3 MP Angle 9°, 15° GH 1,2,3	RP GH 1,2,3 - Angle 17 GH 1,2,3 - Angle 30	GH 2 Angle 15°, 25° NP,SP,WP	Subject Device has a similar design to the primary device and reference device. (Note: In the Zest locator image the screw is not shown, but basically the Subject Device and the Reference Devices share similar design, clinical use and technological characteristics)
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No Differences
Surface Treatment	CNC Machined	CNC Machined	CNC Machined	No Differences

	with or without coloring anodize	with or without coloring anodize	with or without coloring anodize	
Connection	Internal Hex Conical Connection	Internal Hex	Internal Hex Conical Connection	No differences
Related Components	 Silicon Cap soft, ExtraSoft:	 Silicon caps soft, standard, strong, housing cap	Metal Caps, Silicon Caps 	No Differences
Operation	Overdenture Screw Retained	Screw Retained	Overdenture Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences

1.6. **Table No.7**	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***Straight Anatomic Abutment***	***Straight Anatomic Abutment***	***Transfer Abutment***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	UNIQA Dental Ltd	
510k	K251188	K180598	K180598	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	Straight Abutment with Shoulder 	Straight Anatomic Abutment 	Transfer Abutment 	Subject Device is the same as Primary Device and Similar to Reference Device.
Dimensions mm *Gingival Height=GH*	RP GH 5 Ø 6 GH 1,2,3,4,5	GH 1,2,3,4 RP,WP	GH 1,2,3,4,5 MP,RP,WP 4.4,5.0, 6.0	The specifications of the Subject Device fall within the limits of both the Primary Device and the Reference Device.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface	CNC Machined	CNC Machined	CNC Machined	No differences
Connection	Internal Hex	Internal Hex	Conical Connection	Subject Device is the same as

				Primary Device
Compatible Implant System	UNIQA Internal Hex Implant	UNIQA Internal Hex Implant	UNIQA Conical Connection Implant	Subject Device is the same as Primary Device.
Operation	Cement Restoration	Cement Restoration	Cement Restoration	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences

1.7. **Table No.8**	Subject Device	Primary Device		
Technical Characteristic	***Straight Abutment***	***Transfer Abutment***		***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd		
510k	K251188	K180598		
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment		No differences
Product Image	Straight Abutment 	Transfer Abutment 		Subject Device is similar to Primary Device
Dimensions mm *Gingival Height=GH*	RP Ø 4.5, 5,6,7 GH-1,2,3,4,5 MP Ø 4.5 GH-1,2,3,4,5	GH 1,2,3,4,5 MP,RP,WP 4.4,5.0, 6.0		Subject Device is in the limits of Primary Device.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.		No differences
Surface	CNC Machined	CNC Machined		No differences
Connection	Conical Connection	Internal Hex Conical Connection		No differences
Operation	Cement Restoration	Cement Restoration		No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization		No differences

1.8. **Table No.9**	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***15 ° / 25° Abutment***	***15 ° / 25° Angled Anatomic Abutments/ Abutment with Shoulder***	***Cementable angulated abutment 10°/15°/20°/25°***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	MIS Implant Technologies Ltd	
510k	K251188	K180598	K163349, K040807	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	15 ° / 25° Abutment 	15 ° / 25° Angled Anatomic Abutments/ Abutment with Shoulder 	*Cementable angulated abutment* 	Subject Device is similar to Primary Device and Reference Device
Dimensions mm *Gingival Height=GH*	Conical MP - GH 1,2,3 - Angle 15, 25 RP - GH 1,2,3,4 - Angle 15, 25	RP GH 1,2,3,4 - Angle 15, 25	NP,RP,WP GH 1,2,3 – Angle 10, 15, 20,25 Total Length – 9, 10, 11,12	Subject Device is similar and is within the limits of Primary Device and Reference Device
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface	CNC Machined	CNC Machined	CNC Machined	No differences
Connection	Conical connection	Internal Hex	Internal Hex Conical Connection	Subject Device is similar and is within the limits of Primary Device and Reference Device.
Operation	Cement Restoration	Cement Restoration	Cement Restoration	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences

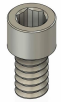
1.9. Table No.10	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***Straight Multi Unit Abutments D-Type***	***Straight Multi Unit Abutments D-Type***	***Straight Multi Unit Abutments***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	MIS Implant Technologies Ltd	
510k	K251188	K180598	K163349, K040807	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	Straight Multi Unit Abutments D-Type 	Straight Multi Unit Abutments D-Type 	Straight Multi Unit Abutments 	Subject Device is similar to Primary Device
Dimensions mm *Gingival Height=GH*	RP - GH 1,2,3,4,5 MP - GH 1,2,3,4,5	RP GH 1,2,3,4	NP, RP, WD Diameter: Regular GH 1,2,3,4,5	Subject Device is similar and is within the limits of Primary Device and Reference Device. UNIQA K180598 consists also of Multi Unit V-Type for conical connection Heights 0.5,1,2,3,4,5.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	No differences
Connection	Internal Hex Conical Connection	Internal Hex	Internal Hex Conical Connection	No differences
Related Components	 Healing Caps, Temporary sleeves, screws	 Healing Caps, Temporary sleeves, screws	 Healing Cap, Temporary cylinder, screws	No differences
Operation	Screw Retained	Screw Retained	Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences

	Subject Device	Primary Device	Reference Device	

1.10. Table No.11				
Technical Characteristic	***17°/30° Angled Multi Unit Abutments D- Type***	***17°/30° Angled Multi Unit Abutments D- Type***	***NobelActive Multi Unit Abutment***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	Nobel Biocare AB	
510k	K251188	K180598	K072570	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	17°/30° Angled Multi Unit Abutments D- Type 	17°/30° Angled Multi Unit Abutments D- Type 	*NobelActive Multi Unit Abutment* 	Subject Device is similar to Primary Device
Dimensions mm Gingival Height=GH	MP - GH 1,2,3,4 - Angle 17, 30 RP - GH 1,2,3,4 - Angle 17, 30	RP GH 1,2,3 - Angle 17, 30	NP,RP GH 1.5,2.5,3.5,4.5 Angle 0, 17, 30	Subject Device is similar and is within the limits of Primary Device and Reference Device
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V	No differences Subject Device is similar to Primary Device
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	No differences
Connection	Internal Hex Conical Connection	Internal Hex	Internal Hex Conical Connection	No differences
Related Components	Healing Caps, Temporary sleeves, screws	Healing Caps, Temporary sleeves, screws	Healing Caps, Temporary sleeves, screws	No Differences
Operation	Screw Retained	Screw Retained	Screw Retained	No Differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Sterile Gamma Irradiation, Single Use	Subject Device the same as Primary Device

1.11. Table No.13	Subject Device	Primary Device	Reference Device	
Technical Characteristic	***Straight Multi Unit Abutments V-Type***	***Straight Multi Unit Abutments V-Type***	***Straight Multi Unit Abutments***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	MIS Implant Technologies Ltd	
510k	K251188	K180598	K163349, K040807	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	Straight Multi Unit Abutments V-Type 	Straight Multi Unit Abutments V-Type 	Straight Multi Unit Abutments 	No differences
Dimensions mm *Gingival Height=GH*	RP - GH 0.5,1,2,3,4,5, 6 MP - GH 0.5,1,2,3,4,5	RP GH 0.5,1,2,3,4,5	GH 1,2,3,4,5 NP,RP,WP	Subject Device is similar to the Primary Device and Reference Device. The 6mmL for internal hex is a minor change since this a straight abutment which exist in other UNIQA K180598 abutments designs such as: Healing caps 2-7mm, ball attachment 0.5-7mm, UNIQA Multi Unit D-type for conical connection.
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	No differences
Connection	Internal Hex Conical Connection	Internal Hex	Internal Hex Conical Connection	No differences
Related Components	 Healing Cap, Sleeve, screws	 Healing Cap, sleeve, screws	Healing Cap, cylinder sleeve, screws	No differences
Operation	Screw Retained	Screw Retained	Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	No differences
	Subject Device	Primary Device	Reference Device	

1.12. Table No.14				
Technical Characteristic	***Temporary Sleeve for Multi Unit***	***Temporary Sleeve for Multi Unit***	***Temporary Abutment for Multi Unit Abutment***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	Nobel Biocare AB	
510k	K251188	K180598	K072570	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	Temporary sleeve for MUA 	Temporary sleeve for MUA 	Temporary Abutment for Multi-unit 	No differences
Dimensions mm *Gingival Height=GH*	Internal/Conical Legnth-1.5,3,4,6,8,12 for V-type	Internal Total length - 10mm, 12mm Conical Total length - 12mm	Length 10mm 3.0, NP, RP, WP 1.5, 3 Slim Length 6.5, 7.5	No differences The subject device is in the limits of Primary Device and Reference Device
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	CNC Machined with or without coloring anodize	No differences
Connection	Internal Hex Conical Connection	Internal Hex Conical Connection	For all Nobel Platforms: External hex, Internal Conical Connection, Internal Tri-channel	No differences
Operation	Screw Retained	Screw Retained	Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization	Non Sterile, Single Use Steam sterilization	Sterile Gamma Irradiation, Single Use	Subject Device the same as Primary Device

1.13. Table No.15			
Technical Characteristic	***Abutment Screws***	***Abutment Screws***	***SE Discussion***
Manufacturer	UNIQA Dental Ltd	UNIQA Dental Ltd	
510k	K251188	K180598	
Product Code Regulation Description	NHA Endosseous dental implant abutment	NHA Endosseous dental implant abutment	No differences
Product Image	 Screw for MUA sleeve, D-type / D-type s5  Screw for MUA sleeve D-type s3  Screw for MUA sleeve D-type Torx6  Screw for MUA sleeve D-type s6 Torx6  Screw for MUA sleeve D-type Long Torx6  Screw for MUA sleeve V-type / M-Type  Screw for MUA sleeve V-type Torx6 / M-type Torx6	 Screw for MUA sleeve, D-type  Screw for MUA sleeve, C-type  Screw for abutment /abutment Mini / angled abut.	Added screws has a slight change which raise no difference as verified by static and fatigue test.

<table>
<tr>
<td></td>
<td>
 Screw for MUA sleeve V-type s5
 Screw for MUA sleeve V-type s5 Torx6
 Screw for MUA sleeve V-type s6 Torx6
 Screw for abutment / angled abut.
</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimensions mm</td>
<td>
<table>
<tr><th>Screw type</th><th>Length</th><th>Shaft diameter</th></tr>
<tr><td>Screw for MUA sleeve, D-type / D-type s5</td><td>3.9
4.5</td><td>1.4
1.4</td></tr>
<tr><td>Screw for MUA sleeve D-type s3</td><td>5.2</td><td>1.15</td></tr>
<tr><td>Screw for MUA sleeve D-type Torx6</td><td>5.2
4.2</td><td>1.4
1.38</td></tr>
<tr><td>Screw for MUA sleeve D-type s6 Torx6</td><td>4.2</td><td>1.5</td></tr>
<tr><td>Screw for MUA sleeve D-type Long Torx6</td><td>4.5</td><td>1.4</td></tr>
<tr><td>Screw for MUA sleeve V-type</td><td>3.9
5.2
5</td><td>1.5
1.5
1.5</td></tr>
<tr><td>Screw for MUA sleeve V-type Torx6</td><td>5.2
4</td><td>1.8
1.88</td></tr>
<tr><td>Screw for MUA sleeve V-type s5</td><td>5</td><td>1.5</td></tr>
<tr><td>Screw for MUA sleeve V-type s5 Torx6</td><td>5</td><td>1.4</td></tr>
<tr><td>Screw for MUA sleeve V-type s6 Torx6</td><td>4.2</td><td>1.8</td></tr>
<tr><td>Screw for MUA sleeve M-type</td><td>3.9</td><td>1.6</td></tr>
<tr><td>Screw for MUA sleeve M-type Torx6</td><td>4.42</td><td>1.6</td></tr>
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</td>
<td>
<table>
<tr><th>Screw type</th><th>Length</th><th>Shaft diameter</th></tr>
<tr><td>Screw for MUA sleeve, D-type</td><td>3.9</td><td>1.5</td></tr>
<tr><td>Screw for angled MUA, D-type</td><td>6.8</td><td>1.4</td></tr>
<tr><td>Screw for abutment</td><td>8.3
8.1</td><td>1.4
1.4</td></tr>
<tr><td>Screw for MUA sleeve, V-type</td><td>3.9</td><td>1.5</td></tr>
<tr><td>Screw Mini Conical</td><td>10.2</td><td>1.54</td></tr>
<tr><td>Screw Regular Conical</td><td>8.4</td><td>1.93</td></tr>
<tr><td>Screw for MUA sleeve, C-type</td><td>4.3</td><td>1.54</td></tr>
</table>
</td>
<td>The subject device is in the limits of Primary Device. Assembling connection-implant/ abutment/ screw has been verified by static and fatigue test according to ISO 14801.</td>
</tr>
</table>

	Screw for abutment Torx6 Internal Hex RP	7.7	1.4	
	Screw for abutment Internal Hex RP	8	1.4	
		7.5	1.4	
		10.2	1.13	
		8.4	1.55	
		7.5	1.55	
	Screw for abutment Conical	10.2	1.54	
		10.2	1.13	
		8.4	1.93	
		8.4	1.55	
		7.5	1.55	
	Screw for angled MUA D-type Conical	8.9 7.3	1.25	
Material	Titanium alloy Ti-6Al-4V-ELI.		Titanium alloy Ti-6Al-4V-ELI.	No differences
Surface Treatment	CNC Machined with or without coloring anodize		CNC Machined with or without coloring anodize	No differences
Connection	Internal Hex Conical Connection		Internal Hex Conical Connection	No differences
Operation	Screw Retained		Screw Retained	No differences
Sterilization	Non Sterile, Single Use Steam sterilization		Non Sterile, Single Use Steam sterilization	No differences

12 Summary of Equivalence:

UNIQA® Dental Implants System, Subject Device is similar in design, intended use, raw material, specifications and surface to its similar devices Primary Device UNIQA K180598, and References Devices: MIS® K163349, K040807, K180282, Nobel Biocare® K142260, K072570, SGS® K182219 and ZEST LOCATOR® K252944. The SE Table presented the technical parameters of each device compared to the Primary Device and/or Reference Device evaluating the differences. No significant differences are presented by UNIQA Subject Device. The UNIQA fatigue test results demonstrated high mechanical resistance (per ISO 14801). Fatigue and static test protocols are presented in the Mechanical Testing Section. The differences between Subject Device and Predicate Device and/or Reference Device did not alter the intended use and new issues of safety and effectiveness were not raised. Therefore, it can be considered that Subject Device is substantial equivalent to its Primary Device and/or Reference Device.

13 Performance Testing:

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

Fatigue Test and Static Tests were conducted in accordance with:

ISO 14801:2016 Dentistry – Implants - Dynamic fatigue test for endosseous dental implants; The selected fatigue-test configurations represent the worst-case implant–abutment loading conditions, including Regular and Mini Platforms, 30° Multi-Unit Abutments, 30° Ball Attachments. The results demonstrated high mechanical performance of the UNIQA® Dental Implants and Abutments.

Sterilization Validation Test was conducted:

in order to ensure safety and effectiveness related to UNIQA® Dental Implants for additional VDmax method- Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met. The test was conducted in accordance with ISO 11737-1:2018 /AMD 1:2021, ISO 11737-2:2019, ISO 11137-1:2006 /Amd 2:2018, ISO 11137-2:2013/Amd 1:2022, AAMI TIR /ISO 13004:2022-10.

Endotoxin Testing was conducted in accordance with:

USP<85>Bacterial Endotoxins Test, USP <161> Medical Devices Bacterial Endotoxin and Pyrogen Tests. Endotoxin (LAL) testing is performed to ensure that bacterial endotoxin

levels on sterile dental implants remain below the allowable limit to prevent pyrogenic reactions in patients, and all UNIQA° test results have met the acceptance criteria.

Steam Sterilization Test was conducted in accordance with:

ISO 17665:2024 Sterilization of health care products Moist heat. The test was conducted in order to ensure safety and effectiveness or additional steam sterilization method related to UNIQA® Dental Abutments - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Packaging Testing was conducted in accordance with:

ISO 11607-1:2019 /Amd 1:2023, ASTM F 1929-15, ASTM F88/F88M-21; to verify the integrity of UNIQA° sterile packaging and that confirm that the sterile barrier is maintained.

Biocompatibility Testing was conducted:

Cytotoxicity test was conducted in accordance with ISO 10993-11:2017, USP-NF – <151> Pyrogen Test, ISO 10993-5:2009 ; The test covered titanium abutments (Ti6Al4V Eli), anodized abutments to verify that the manufacturing process and cleaning process did not change the biocompatibility profile UNIQA. Test results met the criteria. Material mediated pyrogenicity test was conducted in accordance with ISO 10993-11, USP-NF – <151> Pyrogen Test (2017) - all test results met the criteria. The test item met the requirements for the absence of pyrogens.

Surface Treatment Test

UNIQA's Dental implants are provided in two options of surface treatment (1) 'SBA' - Sand Blast of Aluminum Oxide SLA following acid etched (2)'Pure&Porous' - Sand Blast of Hydroxyapatite Calcium Phosphate following acid etched; X-ray Photoelectron Spectroscopy (XPS) and Energy Dispersive Spectroscopy (EDS) were conducted to verify elemental composition and surface cleanliness. Testing confirmed that the modified surfaces met the expected morphological and chemical characteristics, including appropriate cleanliness and composition consistent with the device's design specifications.

MRI Safety

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all

compatible implant bodies, dental abutments, and fixation screws) and material compositions. The rationale addressed parameters per the FDA Guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”, including magnetically induced displacement force and torque.

Risk Management was conducted in accordance with:

EN ISO 14971:2019 Medical devices – Application of risk management to medical devices.

The results of the non-clinical testing demonstrated that UNIQA Subject Devices met the established performance specifications per intended use. The non-clinical testing also demonstrated that UNIQA Subject Devices do not raise different questions of substantial equivalence when compared to the Primary Device and References Devices.

14 Conclusion:

As verified by Substantial Equivalence, Risk Management and Non-Clinical Testing UNIQA® Dental Implants System shares similarity to its Primary Device and References Devices in terms of intended use, indication for use, raw material, technological characteristics and performance. Therefore, UNIQA® Dental Implants system is substantially equivalent to its predicate devices.