



August 29, 2019

SGS International Ltd
% Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22815 Ventura Blvd
Woodland Hills, California 91364

Re: K182219

Trade/Device Name: SGS® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 10, 2019
Received: July 31, 2019

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <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,

for

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure



Indication for Use Statement

510(k) Number (if known):

K182219

Device Name:

SGS® Dental Implants System

Indications for Use (*Describe*)

Indications for Use:

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.

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*)

510(k) Summary (21 CFR 807.92)

510(k) Number K182219

- 1 Type of Submission Premarket Notification (21 CFR 807.90(e)) 510(k) Traditional
- 2 Submission Owner SGS International Ltd
Michaeli Shabtai – CEO
Karolyi Istvan Street 1-3.
Budapest, Hungary
H 1047, Hungary
Telephone Number +36-309611579
Facsimile (Fax) Number +36-309611579
- 3 Official Correspondent Sterling Medical Registration
Contact Person Daniela Levy - Regulatory Consultant
22815 Ventura blvd.
Woodland Hills, CA 91364
Phone: 1-213-787-3027
Email: sterlingmedical2017@gmail.com
- 4 Prepared Date August 28, 2019
- 5 Device Trade Name SGS® Dental Implants System
- 6 Regulation Description Endosseous Dental Implants Abutment
- 7 Classification
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:
SGS International Ltd K133362;

Reference Devices: UNIQA Dental Ltd K180598; A.B.Dental Devices K112440; Osstem Implant Co Ltd K182091;

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: :

SGS® Dental Implants System is consist of endosseous form dental implants, internal hex implants, tapered design; cover screws, healing caps and abutment systems; Dental Implants:

P7N Narrow Conical Implant, Internal Hex available as follow:

Diameter 3.2 mm Length 8 mm

P1D Conical Groovy Double Connection Implant, Internal hex Conical Connection available as follow:

Diameter 3.5, 3.75, 4.2, 5, 6 mm Length 8, 10, 11.5, 13, 16.

P5D Conical Groovy Double Connection Implant, Internal hex Conical Connection available as follow:

Diameter 3.5, 3.75, 4.2, 4.5, 5, 6 mm Length 8, 10, 11.5, 13, 16.

P7D Conical Groovy Double Connection Implant, Internal hex Conical Connection available as follow:

Diameter 3.5, 3.75, 4.2, 4.5, 5, 6 mm Length 8, 10, 11.5, 13, 16.

Dental Abutments consist of:

Healing Abutments, Anatomic Straight Abutments, Straight Abutments, Straight Abutments Narrow/Wide, PEEK Temporary Abutment, Abutments for bars, Angular Anatomic Abutments Ti, Angular Abutments Slim/Narrow, Multi-Base Angular Abutment, Angular Ball Attachment, S-lock Straight/Angular Abutment, Easy-Fix Angular Abutment, Straight/One-piece angular Multi-unit Abutment, Ball Attachments, Abutment for temporary restoration, Easy Fix Abutments Straight/Angular, Smart Lock abutments Straight/Angular, Flat connection abutments for casting, overdenture attachments. Titanium abutments are CNC machined with no anodized surface.

11 Indication for Use: :

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.

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 :

SE Table - Indication for Use:

	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	UNIQA Dental Ltd
K Number	K182219	K133362	K180598
Indication for use	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.	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. Two Stage Implants: P1, P7, P7N. One Stage: P7S, P9S. One Stage & One-Piece 3.0 mm diameter implants: P7S, P9S 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: P9S permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis, and protection of graft sites. PEEK Temporary Abutments are not to exceed 30 days.	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: #UC1 & #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.
	Reference Device	Reference Device	Reference Device
	Osstem Implant Co Ltd	A.B. Dental Devices	
K Number	K182091	K112440	
Indication for use	Osstem Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	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. I7 Integral implant, I5 Conical implant, P15 Temporary abutment,	

		P12-T,L Temporary flat connection abutment, and P16 adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	
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SE - Dental Implants

Characteristic	Candidate P7N Narrow Conical Implant	Primary Predicate P7 Conical Groovy Implant
510(k) number	TBD	K133362
Manufacturer	SGS International Ltd.	SGS International Ltd.
Product Name	P7N Narrow Conical Implant	P7 Conical Groovy Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread
Measurements Ø / Length mm	3.2Ø: 8	3.2Ø : 8, 10, 11.5 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5.0Ø: 8, 10, 11.5, 13, 16 6.0Ø: 8, 10, 11.5, 13, 16
Connection Type	Internal Hex	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Calcium Phosphate	Calcium Phosphate
Self tapping	Yes	Yes
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

Characteristic	Candidate P1D Conical Groovy Double Connection Implant	Primary Predicate P1 Screw Type Groovy Implant
510(k) number	TBD	K133362
Manufacturer	SGS International Ltd.	SGS International Ltd.
Product Name	P1D Conical Groovy Double Connection Implant	P1 Screw Type Groovy Implant
Thread Design	Straight	Tapered, Double Thread
Measurements Ø / Length mm	3.5Ø : 8, 10, 11.5, 13, 16 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 5Ø: 8, 10, 11.5, 13, 16 6Ø: 8, 10, 11.5, 13, 16	3.2Ø : 8, 10, 11.5 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5Ø: 8, 10, 11.5, 13, 16 6Ø: 8, 10, 11.5, 13, 16
Connection Type	Internal conical	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Calcium Phosphate	Calcium Phosphate
Self tapping	Yes	Yes
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

Characteristic	Candidate P5D Conical Groovy Double Connection Implant	Primary Predicate P7 Conical Groovy Implant
510(k) number	TBD	K133362
Manufacturer	SGS International Ltd.	SGS International Ltd.
Product Name	P5D Conical Groovy Double Connection Implant	P7 Conical Groovy Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread
Measurements Ø / Length mm	3.5Ø : 8, 10, 11.5, 13, 16 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5.0Ø: 8, 10, 11.5, 13, 16 6.0Ø: 8, 10, 11.5, 13, 16	3.2Ø : 8, 10, 11.5 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5.0Ø: 8, 10, 11.5, 13, 16 6.0Ø: 8, 10, 11.5, 13, 16
Connection Type	Internal conical	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Calcium Phosphate	Calcium Phosphate
Self tapping	Yes	Yes
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

Characteristic	Candidate P7D - Dental Implant with Double Connection	Primary Predicate P7 Conical Groovy Implant
510(k) number	TBD	K133362
Manufacturer	SGS International Ltd.	SGS International Ltd.
Product Name	P7D - Dental Implant with Double Connection	P7 Conical Groovy Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread
Measurements Ø / Length mm	3.5Ø : 8, 10, 11.5, 13, 16 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5.0Ø: 8, 10, 11.5, 13, 16 6.0Ø: 8, 10, 11.5, 13, 16	3.2Ø : 8, 10, 11.5 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5.0Ø: 8, 10, 11.5, 13, 16 6.0Ø: 8, 10, 11.5, 13, 16
Connection Type	Internal conical	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Calcium Phosphate	Calcium Phosphate
Self tapping	Yes	Yes
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

SE - Dental Abutments:

	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	UNIQA Dental Ltd
K Number		K133362	K180598
Product Name	Healing Abutments (HD,HND,HW7D,HW8D,HWD)	Healing Abutments (HN,HNN,HWN,H,HN, HW)	Healing Cap # UOHX
Dimensions	Narrow, Length: wide 2,3,4; Normal, Length: 2,3,4,5,6 Wide, Length: 3,5	Narrow, Length: 2,3,4 Normal, Length: 2,3,4,5,6 Wide, Length: 3,5	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
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal conical	Internal Hex	Internal conical
	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	UNIQA Dental Ltd
K Number		K133362	K180598
Product Name	Anatomic Straight Titanium Abutment S1AD	Anatomic Straight Titanium Abutment S1A, S1AN	Transfer Abutment #UOTX
Dimensions	Normal Profile: Height 1, 2, 3 mm	Narrow: Straight Anatomic Abutment-Profile Height 1 mm Normal: Profile Height 1, 2, 3 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)
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Conical	Internal Hex	Internal Conical
	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	UNIQA Dental Ltd
K Number		K133362	K180598
Product Name	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8	Straight Titanium Abutment S1N,S1WN, S1,S1N,S1W	Transfer Abutment #UOTX
Dimensions	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length	Narrow: Narrow, Wide - Length:9 Normal: Length: 5, 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9	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
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal conical	Internal Hex	Internal conical
	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	
Product Name	Anatomic Straight PEEK Abutment S1AN-PEEK	Anatomic Straight PEEK Abutment S1A-PEEK	
K Number		K133362	
Dimensions	Diameter: 3.0, Profile:1	Diameter: 3.75 Profile:1,2,3	
Material	PEEK-CLASSIX	PEEK-CLASSIX	
Connection	Internal Hex	Internal Hex	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	A.B. Dental Devices	
K Number		K112440	
Product Name	Abutment for bars S1T, S1TD , S1TN	P7 Anti rotation aesthetic abutment	
Dimensions	Diameter:3.75 Height: 0.5, 1.5, 2.5, 3.5; NP : 3.0 dmm, Height: 0.5, 1.5, 2.5	Diameter:3.75 Height: 1, 2, 3;	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal Hex/conical	Internal Hex	
	Candidate	Reference Device	Reference Device
	SGS International	UNIQA Dental Ltd	
K Number		K180598	
Product Name	Angular Abutments S2D-29	Angled Multi Unit Abutment, MUA, D-type #UAMD	
Dimensions	Diameter: 3.75, Length: 11	Diameter:3.75, regular platform Height: 1, 2, 3	
Angulations	29°	Titanium alloy Ti-6Al-4V-ELI.	
Material	Titanium alloy Ti-6Al-4V-ELI.	17°, 30°	
Connection	Internal conical	Internal Hex/	

	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International ltd	UNIQA Dental ltd
K Number		K133362	K180598
Product Name	Angular Abutments S2D, S2S, S2DS	Anatomic Angular Titanium Abutment S2A	UABR Angled Abutment
Dimensions	NP Diameter: 3.75, Length: 11 Slim Diameter: 3.75, Length: 11	Normal: Height 1,2, 3 Length 9, 11	Diameter: Regular; Length 9,12 - Angle 15, 25
Angulations	15°, 25°	15°, 25°	10°, 15°, 25°
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal conical	Internal Hex	Internal
	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	UNIQA Dental ltd
K Number		K133362	K180598
Product Name	Angular Titanium Abutment, S2N, S2AN, S2AD, S2LD	Angular Titanium Abutment, S2N, S2L, S2A	UAAR Angled Anatomic abutment
Dimensions	Narrow: Angle 25° - length 9 mm Narrow Anatomic: Angle 15°, 25° - Height 1,2 mm Regular Anatomic: 3.75mm, Angle 15°, 25° - Height 1,2,3,4 Regular: 3.75mm, Length 13mm, Angle 15°, 25° -	Narrow: Angle 15°, - length 9 mm Normal: Angle 15°, 25° - Length 9, 11 mm Normal: Height 1,2, 3 Length 9, 11	Diameter: Regular Profile Height 1,2,3,4 - Angle 15 Height 1,2,3,4 - Angle 25
Angulations	15°, 25°	15°, 25°	15°, 25°
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex/conical	Internal Hex	Internal
	Candidate	Reference Device	Reference Device
	SGS International	UNIQA Dental ltd	
K Number		K180598	
Product Name	Multi-Base Angular Abutment S7	Angled Multi Unit Abutment, MUA, D-type #UAMD	
Dimensions	Diameter: 3.75 Height: 1, 2, 3	Diameter: 3.75, regular platform Height: 1, 2, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	30°	17°, 30°	
Connection	Internal Hex	Internal Hex	

	Candidate	Reference Device	Reference Device
	SGS International Ltd	Osstem Implant Co Ltd	
K Number		K182091	
Product Name	S3-S7 - Angular Ball Attachment	Port Angled Abutment& Port Angled Abutment Head	
Dimensions	Diameter:3.75 Height: 1, 2, 3	Diameter:4.63-4.82 Height: 1, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	10°,17°, 30°	
Connection	Internal Hex	Internal Hex	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	UNIQA Dental Ltd	
K Number		K180598	
Product Name	S4-S7 - Angular Abutments for immediate loading	Angled Multi Unit Abutment, MUA, D-type #UAMD	
Dimensions	Diameter:3.75 Height: 1, 2, 3	Diameter:3.75, regular platform Height: 1, 2, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	17°, 30°	
Connection	Internal Hex	Internal Hex	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	Osstem Implant Co Ltd	
K Number		K182091	
Product Name	S35-S7 - S-lock Angular Abutment	Port Angled Abutment& Port Angled Abutment Head	
Dimensions	Diameter:3.75 Height: 1, 2, 3	Diameter:4.63-4.82 Height: 1, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	10°,17°, 30°	
Connection	Internal Hex	Internal Hex	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	Osstem Implant Co Ltd	
K Number		K182091	
Product Name	S5-S7 -Easy Fix Angular Abutment	Port Angled Abutment& Port Angled Abutment Head	
Dimensions	Diameter:3.75 Height: 1, 2, 3	Diameter:4.63-4.82 Height: 1, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	10°,17°, 30°	
Connection	Internal Hex	Internal Hex	

	Candidate	Reference Device	Reference Device
	SGS International Ltd	UNIQA Dental Ltd	
K Number		K180598	
	S17 - The one-piece angular Multi-unit Abutment	Angled Multi Unit Abutment, MUA, D-type #UAMD	
Dimensions	Diameter:3.75 Height: 1, 2, 3,4,5	Diameter:3.75, regular platform Height: 1, 2, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	17°, 30°	
Connection	Internal Hex	Internal Hex/	
<i>Related components</i>	H-S16/S17 healing cap, T-S16/S17 Titanium sleeve, TW-S16/S17 Titanium sleeve, T3-S16/S17 adaptor	The same	
	Candidate	Reference Device	Reference Device
	SGS International	UNIQA Dental Ltd	
K Number		K180598	
Product Name	S7D Multi-Base Angular Abutment	Angled Multi Unit Abutment, MUA, D-type #UAMD	
Dimensions	Diameter:3.75 Height: 1, 2, 3	Diameter:3.75, regular platform Height: 1, 2, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17, 30°	17°, 30°	
Connection	Conical	Internal Hex/conical	
Related accessories	H-S6/S7 healing cap, T-S6/S7 Titanium sleeve, TW-S6/S7 Titanium sleeve, T3-S6/S7 adaptor	<i>The same</i>	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	UNIQA Dental Ltd	
K Number		K180598	
	S17D - The one angular Multi-unit Abutment	Angled Multi Unit Abutment, MUA, D-type #UAMD	
Dimensions	Diameter:3.75 Height: 1, 2, 3, 4, 5	Diameter:3.75, regular platform Height: 1, 2, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	17°, 30°	

Connection	Internal conical	Internal Hex/	
Related components	H-S16/S17 healing cap, T-S16/S17 Titanium sleeve, TW-S16/S17 Titanium sleeve, T3-S16/S17 adaptor,	The same	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	UNIQA Dental Ltd	
K Number		K180598	
Product Name	S16 , S16D - The straight one-piece Multi-unit Abutment	Straight Multi Unit Abutment, MUA, D-type # USMD	
Dimensions	Diameter: 3.75 Height: 1, 2, 3, 4, 5;	Diameter:3.75 Regular platform Height: 1,2, 3,4,	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal hex(S16) / conical (S16D)	Internal hex	
Related components	H-S16/S17 healing cap, T-S16/S17 Titanium sleeve, TW-S16/S17 Titanium sleeve, T3-S16/S17 adaptor	Sleeve, Healing Cap, plastic cap	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	Osstem Implant Co Ltd	
K Number		K182091	
Product Name	S35N, S35D,S35, S-Lock Abutments	Port Abutment	
Dimensions	Narrow Diameter:3.0 Height: 1, 2, 3; Regular Diameter: 3.75 Height: 1,2, 3,4,5,6	Diameter: 3.5, 3.7, 4.1, 4.8, 5.1 Height: 1, 2, 3, 4, 5, 6, 7	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal conical	Internal hex	
	Candidate	Primary Predicate	Reference Device
	SGS International	SGS International	UNIQA Dental Ltd
K Number		K133362	K180598
Product Name	Ball Attachment S3D	Overdenture Ball attachment S3N, S3	Ball Attachment #UBAR
Dimensions	Normal: Length:1,2,3,4,5,6	Narrow: Length:1,2,3,4 Normal: Length:1,2,3,4,5,6,7	Regular platform: Height 0.5,1,2,3,4,5,6, 7
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal conical	Internal Hex	Internal

	Candidate	Reference Device	Reference Device
	SGS International ltd	A.B. Dental Devices	UNIQA Dental ltd
K Number		K112440	K180598
Product Name	S4D Temporary Abutment for immediate loading	P16 Straight adaptor Temporary Abutment P15	Straight Multi Unit Abutment, MUA, C-type (Cat#UOMM)
Dimensions	Narrow Diameter 3.0, Profile length 0.5, 1.5, 2.5,3.5 Regular Diameter 3.75, Profile length 0.5, 1.5, 2.5,3.5	Diameter 3.0, Profile length 1,2,3 Diameter 3.75, Profile length 1,2,3,4,5,6,7	Mini Diameter: 4.0 Height 1, 2,3,4 (#UOMM) Regular Diameter: 4.0, 5.0, 6.0 Height 1, 2,3,4,5 (5mm not for 4Ø) (#UOMR)
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex/conical	Internal Hex	Internal conical
	Candidate	Reference Device	
	SGS International ltd	Osstem Implant Co Ltd	
K Number		K182091	
Product Name	S5D Easy Fix Abutment S8D Smart lock abutment	Port Abutment	
Dimensions	Narrow Diameter 3.0, Profile length 0.5, 1.5, 2.5,3.5 Regular Diameter 3.75, Profile length 0.5, 1.5, 2.5,3.5 (S8D) - Regular Diameter 3.75, Profile length 1,2,3,4,5,6	Diameter: 3.5, 3.7, 4.1, 4.8, 5.1 Height: 1, 2, 3, 4, 5, 6, 7	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal conical	Internal hex	
	Related components: Metal/Silicon caps	Related components: Metal/Silicon caps	

	Candidate	Reference Device	Reference Device
	SGS International ltd	Osstem Implant Co Ltd	
K Number		K182091	
Product Name	S5D-S7D Easy fix angular abutment	Port Angled Abutment& Port Angled Abutment Head	
Dimensions	Diameter: 3.75 Height: 1, 2, 3;	Diameter:4.63-4.82 Height: 1, 3	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Angle	17°, 30°	10°,17°, 30°	
Connection	Internal conical	Internal Hex	

	Candidate	Reference Device	Reference Device
	SGS International Ltd	UNIQA Dental Ltd	
<i>K Number</i>		K180598	
<i>Product Name</i>	S8D-15 - Smart Lock angular abutments	Angled Multi Unit Abutment, MUA, D-type #UAMD	
<i>Dimensions</i>	Diameter: 3.75 Height: 1.5, 3;	Diameter:3.75 regular platform Height: 1, 2, 3	
<i>Material</i>	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
<i>Angle</i>	15°	17°, 30°	
<i>Connection</i>	Internal conical	Internal Hex/	
	Candidate	Reference Device	Reference Device
	SGS International Ltd	UNIQA Dental Ltd	
<i>K Number</i>		K180598	
<i>Product Name</i>	S15D-PT Flat connection abutment for casting S15D-T Flat connection straight abutment	Angled Multi Unit Abutment, MUA, D-type #UAMD	
<i>Dimensions</i>	Diameter: 3.75 Length 15 mm	Diameter:3.75 Regular platform Height: 1,2,3	
<i>Material</i>	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
<i>Connection</i>	Internal conical	Internal Hex/	

14 Summary of Equivalence:

SE – Indication for Use Discussion -

SGS® Dental Implants - share the same indication for use as its previous submission and current Primary Predicate: SGS® International Ltd K133362. The only difference is that the Primary Predicate SGS® International Ltd K133362 was introducing more implants' design and as such has provided more details for the indication for use. In current submission SGS introduces the same implants' design only having conical connection, as such no differences are applied to the indication for use.

SGS® Dental Abutments - share the same indication for use as its previous submission and current Primary Predicate: SGS® International Ltd K133362; Since SGS® is introducing new abutments design which were not included in previous submission then the following similar reference devices have been indicated: UNIQA Dental Ltd K180598; A.B.Dental Devices K112440; Osstem Implant Co Ltd K182091; Review of the reference devices indication for use raises no differences compare to SGS® but only minor wording

differences, therefore, SGS® Dental Implants/Abutments system is considered to be substantially equivalent to its Primary predicate and reference devices.

SE – Dental Implants, Dental Abutment -

As demonstrated by the substantial equivalent table SGS® Dental Implants System shares similarity to its Primary predicate SGS International Ltd K133362; and Reference Devices: UNIQA Dental Ltd K180598; A.B.Dental Devices K112440; Osstem Implant Co Ltd K182091; in terms of indication for use, intended use, technological characteristics, raw material, design, measurements, surface treatment, sterilization method and performance. Minor differences are related to implants' measurements but are still in the range of the Primary Predicate SGS K133362.

Minor differences are related to the abutments' measurements but are still in the range of the reference devices: UNIQA Dental Ltd K180598; A.B.Dental Devices K112440; Osstem Implant Co Ltd K182091;

The differences have been assessed by Fatigue testing per ISO 14801:2007 which have demonstrated good results, therefore SGS® Dental Implants system is considered to be substantially equivalent to its predicate devices. In respect of the subject SGS Angular Abutments S2D-29 the change of technology from the multi-unit reference device UNIQA Dental Ltd K180598 to single-unit the Angular Abutments S2D-29, was addressed by Fatigue testing per ISO 14801:2007.

15 Performance Testing :

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

Sterilization Validation Test was carried out with SGS to ISO 11137 - 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 - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Biocompatibility - SGS Dental Implants are made of Ti6Al4V ELI using the conventional manufacturing process. Biocompatibility testing per the FDA Guidance *Use of ISO 10993-1* was leveraged from the Primary Predicate.

Fatigue test were 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 SGS® Dental Implants / Abutments.

Risk Assessment was carried out with accordance to ISO 14971.

16 Conclusion

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