DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Southern Implants (Pty) Ltd.
% Linda Schulz
Senior Regulatory Affairs Specialist
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

November 6, 2017

Re: K163634
Trade/Device Name: External Hex Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 23, 2017
Received: October 24, 2017

Dear Linda Schulz:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163634

Device Name

External Hex Implants

Indications for Use *(Describe)*

Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading.
Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

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.

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510(k) Summary

K163634

External Hex Implants

Southern Implants (Pty) Ltd.

November 6, 2017

ADMINISTRATIVE INFORMATION

Manufacturer Name	Southern Implants (Pty) Ltd. 1 Albert Road Irene, South Africa 0062 Telephone: +011 27 12 667 1046 Fax: +011 27 12 667 1029
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Representative/Consultant	Linda K. Schulz, BSDH, RDH Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1-858-792-1235 Fax: +1-858-792-1236 Email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	External Hex Implants
Common Name	Dental implant Dental implant abutment
Classification Name	Implant, endosseous, root form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate	**Device Name**	**K Number**
Biomet 3i (Primary)	3i T3 External Hex Dental implants	K133049
Reference Predicates		
NSI Inc	Endosseous implant and accessories (NSI Hexed and Non-Hexed Implant System)	K003620
NSI Inc	Endosseous implant and accessories (NSI Hexed and Non-Hexed Implant System)	K020617
Southern Implants Inc.	Endosseous implant and accessories	K082651
Northern Implants, LLC	Endosseous implant and accessories	K053478
Southern Implants Inc.	Endosseous implant and accessories	K070841
Southern Implants Inc.	Endosseous implant and accessories	K070905
Biomet 3i	Low Profile Abutment	K092341
Thommen Medical AG	VARIOunite	K160244
Neoss, Ltd.	Neoss TiBase and CoCr Abutments	K150669
AstraTech AB [Dentsply]	OsseoSpeed™ Plus	K120414

INDICATIONS FOR USE

Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading.
Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

SUBJECT DEVICE DESCRIPTION

The subject device consists of four product lines, External Hex Tapered Implants, External Hex Tapered Internal Drive Implants, External Hex Cylindrical Internal Drive Implants, and External Hex Co-Axis Tapered Implants. Internal drive implants are inserted with a removable tool as opposed to a fixture mount. All product line implants have an external hex implant/abutment connection and a grit-blasted surface. External Hex Tapered Implants and CoAxis Implants come in an MSC design with a machined coronal portion. One product line implant, Co-Axis Tapered, has an angled coronal portion.

Implants are available in the following diameters and lengths

Implant Line	Diameter (mm)	Length (mm)	Implant Angle
Ex Hex Tapered	3.25	8.5, 10, 11.5, 13, 15, 18	NA
	4.0	6, 8.5, 10, 11.5, 13, 15, 18	NA
	5.0	6, 8.5, 10, 11.5, 13, 15, 18	NA
Ex Hex Tapered - MSC	3.25	8.5, 10, 11.5, 13, 15, 18	NA
	4.0	6, 8.5, 10, 11.5, 13, 15	NA
	5.0	6, 8.5, 10, 11.5, 13, 15	NA
Ex Hex Tapered Internal Drive	4.0	8.5, 10, 11.5, 13, 15, 18	NA
	4.7	10, 11.5, 13, 15, 18	NA
	5.7	10, 11.5, 13, 15, 18	NA
Ex Hex Cylindrical Internal Drive	3.75	7, 8.5, 10, 11.5, 13, 15, 18, 20	NA
	5.0	6, 7, 8.5, 10, 11.5, 13, 15, 18	NA
	6.0	7, 8.5, 10, 11.5, 13, 15	NA
Ex Hex CoAxis Tapered	3.25	8.5, 10, 11.5, 13, 15, 18	12°
	4.0	8.5, 10, 11.5, 13, 15, 18	12°
	4.0	8.5, 10, 11.5, 13, 15, 18, 20	24°
	4.7	8.5, 10, 11.5, 13, 15, 18	12°
	4.7	8.5, 10, 11.5, 13, 15, 18	24°
Ex Hex CoAxis Tapered - MSC	3.25	8.5, 10, 11.5, 13, 15, 18	12°
	4.0	8.5, 10, 11.5, 13, 15, 18	12°, 24°
	4.7	8.5, 10, 11.5, 13, 15, 18	12°, 24°

Each product line includes corresponding abutments in multiple designs (Cover Screws, Healing Caps, Healing Abutments, Titanium Abutments, Anatomic Abutments, Cosmetic Abutments, Gold Abutments, Chrome Cobalt Abutments, Compact Conical Abutments, Passive Abutments) for cement-retained and screw-retained restorations. All retaining screws compatible with the subject device have been previously cleared in K053478. Retaining screws TSHZ3 and TSH1 were used for mechanical testing according to ISO 14801. Compact Conical Abutments and Chrome Cobalt Abutments are designed for multi-unit restorations. Compact Conical Abutment is available in straight, 17°, and 30° designs. Cosmetic abutments are available in 12° and 24°. All other abutments are straight (0°). Subject Device components are made of unalloyed titanium, titanium alloy, gold alloy, or cobalt-chromium alloy. Material standards for the subject device components are ASTM F67, ASTM F136, ASTM 1537, and ASTM F1562. Small diameter implants and angled abutments are not recommended for the posterior region

Abutment Model	**Abutment Connection Platform**	**Diameters (mm)**	**Angulation**	**Height (mm)**
Cover screws	External Hex	3.5, 5.0	0	4.4, 4.35
	External Hex	5.0	0	4.35
Healing Caps	Compact Conical	4.8	0	4.6, 6.2
	Compact Conical	6.0	0	4.6, 6.2
	Compact Conical	7.0	0	4.6, 6.2
	Compact Conical	9.0	0	4.6, 6.2
Healing abutments	External Hex	4.5	0	2.2, 3, 4, 5, 6, 8
	External Hex	5.5		2.2, 3, 4, 5, 6, 8, 12
	External Hex	6.5	0	2.2, 3, 4, 5, 6, 8, 12
	External Hex	7.5		2.2, 3, 4, 5, 6, 8, 12
Titanium Abutments	External Hex; Engaging and non-engaging	5.0	0	1, 5
	External Hex; Engaging and non-engaging	6.0	0	1, 5
Anatomic Abutments	External Hex; Engaging and non-engaging	3.4	0	2, 3, 5
	External Hex; Engaging and non-engaging	3.43	0	2, 3, 5
	External Hex; Engaging and non-engaging	4.05	0	2, 3, 5
	External Hex; Engaging and non-engaging	5.0	0	2, 3, 5
	External Hex; Engaging and non-engaging	6.0	0	2, 3, 5
Cosmetic Abutments	External Hex; Engaging	3.43	12°, 24°	2.9, 3.5
	External Hex; Engaging	4.05	12°, 24°	3.0
	External Hex; Engaging	5.0	12°, 24°	2.0, 2.6
	External Hex; Engaging	6.0	12°, 24°	2.6
Gold Abutments	External Hex; Compact Conical Engaging and non-engaging	4.05	0	0.5
	External Hex; Compact Conical Engaging and non-engaging	5.0	0	0.5
	External Hex; Compact Conical Engaging and non-engaging	6.0	0	0.5
Chrome Cobalt Abutments	External Hex; Non-engaging	3.40	0	1.5
	External Hex; Non-engaging	4.05	0	1.5
Compact Conical Abutments	External Hex; Engaging (angled) Non-engaging (straight)	3.0	0	2, 3, 4, 5
	External Hex Engaging (angled) Non-engaging (straight)	3.43	17°	3.0
	External Hex Engaging (angled) Non-engaging (straight)	4.05	17°	2.9, 3.9
	External Hex Engaging (angled) Non-engaging (straight)	4.05	30°	4, 5, 6,
	External Hex Engaging (angled) Non-engaging (straight)	5.0	0°	1.58, 2, 3, 4, 5.5
	External Hex Engaging (angled) Non-engaging (straight)	5.0	17°	2.9, 3.9

	External Hex Engaging (angled) Non-engaging (straight)	5.0	30°	4, 5, 6,
	External Hex Engaging (angled) Non-engaging (straight)	6.0	0°	1.58, 2, 3, 4, 5.5
	External Hex Engaging (angled) Non-engaging (straight)	6.0	17°	308, 4.08
	External Hex Engaging (angled) Non-engaging (straight)	6.0	30°	4.3, 5.3, 6.3
Passive Abutments	External Hex Compact Conical	6.0	0	0.4 – 0.6

PERFORMANCE DATA

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included: radiation sterilization validation according to ISO 11137-1 and 11137-2 and steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10-6; Shelf life testing according to ISO, 11607-1, ISO 11607-2, ASTM F88, ASTM 1929, and ASTM 1980; bacterial endotoxin testing according to AAMI/ANSI ST 72, demonstrating acceptable endotoxin limits; biocompatibility testing according to ISO 10993-5 (cytotoxicity), demonstrating acceptable biocompatibility; and mechanical testing according to ISO 14801, demonstrating that the subject device is strong enough for its intended use.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices shown above. Below are summary tables comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.

Comparison of Indications for Use Statements

Subject Device	Indications for Use Statement
External Hex Implants	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.
Primary Predicate Device	
K133049 3i T3 External Hex Dental implants Biomet 3i	3i T3® Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. 3i T3® Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Reference Predicate Devices	
K003620 Endosseous implant and accessories (NSI Hexed and Non-Hexed Implant System) NSI Inc	Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses.
K020617 Endosseous implant and accessories (NSI Hexed and Non-Hexed Implant System) NSI Inc	Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses.

K082651 Endosseous implant and accessories Southern Implants Inc.	Indication for Use: The 24° Co-Axis implant is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. This implant is not intended, nor should it be used, in conjunction with an angled abutment.
K053478 Endosseous implant and accessories Northern Implants, LLC	Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
K070841 Endosseous implant and accessories Southern Implants Inc.	Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially dentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
K070905 Endosseous implant and accessories Southern Implants Inc.	Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches-to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
K092341 Low Profile Abutment Southern Implants Inc.	BIOMET 3i Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.
K160244 VARIOunite Thommen Medical AG	VARIOflex Thommen Medical VARIOflex abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures. VARIOtemp Thommen Medical VARIOtemp abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures.
K150669 Neoss TiBase and CoCr Abutments Neoss, Ltd.	Neoss TiBase: Neoss Abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation. The Neoss TiBase is compatible with the Sirona Dental System inCoris ZI Meso L. All digitally designed copings and/or crowns for use with the Neoss TiBase Abutments are to be designed and milled using the Sirona Dental CAD/CAM System. Neoss CoCr Abutments: Neoss abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.
K120414 OsseoSpeed™ Plus Astra Tech AB [Dentsply]	The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: * replacing single and multiple missing teeth in the mandible and maxilla, * immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, * especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, * immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors.

The subject device and predicate devices are substantially equivalent in intended use, design and function. All predicates are implant systems placed in the maxilla or mandible for single or multi-unit restorations with possible immediate loading. Minor differences in language in the Indications for Use Statement between the subject device and the primary predicate device do not change the intended use of implant placement and function. Compared to the primary predicate, the subject device Indications for Use statement simplifies repeated references to different types of restorations, in varying language, to say crowns, bridges or overdentures.

Subject device implants have an external hex implant/abutment interface and threaded design substantially equivalent to K133049, K003620, K020617, K082651, K053478, K070841, and K070905. They have the same implant surface as K003620, K020617, K082651, K053478, K070841, and K070905. CoAxis implants have the same or a substantially equivalent angle as K082651. Subject device abutments are substantially equivalent in design and material to K053478, K070841, K070905, K092341, K150669 and K120414. Further detail is outlined in the table of technological characteristics below.

Comparison of Technological Characteristics

Comparison	Subject Device	Primary Predicate	Reference Predicates									
	External Hex Implants Southern Implants (Pty) Ltd.	3i T3 External Hex Dental implants Biomet 3i	Endosseous implant and accessories (NSI Hexed and Non-Hexed Implant System) NSI Inc	Endosseous implant and accessories (NSI Hexed and Non-Hexed Implant System) NSI Inc	Endosseous implant and accessories Southern Implants, Inc.	Endosseous Dental Implant System Northern Implants, LLC	Endosseous Dental Implant System Southern Implants, Inc.	Endosseous Dental Implant System Southern Implants, Inc	Low Profile Abutment Biomet 3i	VARIOunite Thommen Medical AG	Neoss TiBase and CoCr Abutments Neoss, Ltd.	OsseoSpeed™ Plus Astra Tech AB [Dentsply]
510(k) Number	K163634	K133049	K003620	K020617	K082651	K053478	K070841	K070905	K092341	K160244	K150669	K120414
IMPLANTS												
Implant Design	Straight, Threaded; Angled (12°, 24°), Threaded	Straight, Threaded	Straight, Threaded	Straight, Threaded	Straight, Threaded; Angled (24°), Threaded	Straight, Threaded	Straight, Threaded; Angled (12°), Threaded	Straight, Threaded	NA	NA	NA	Straight, Threaded
Implant Lengths (mm)	6, 7, 8.5, 10, 11.5, 13, 15, 16, 18, 20	6.5, 8.5, 10, 11.5, 13, 15, 18	7, 8.5, 10, 11.5, 13, 15, 16, 18, 20	7, 10, 11.5, 13, 15	10, 11.5, 13, 15, 18	8.5, 10, 11.5, 13, 15, 18	8.5, 10, 11.5, 13, 15, 18	10.5, 13.5, 16.5	NA	NA	NA	6, 8, 9, 11, 13, 15, 17
Implant Body Diameters (mm)	3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	3.25, 4.0, 5.0, 6.0	3.75, 4.0, 5.0	4.7, 5.7, 6.0	4.7, 5.7	3.25	4.0	3.5, 4.3, 5.0	NA	NA	NA	3.0, 3.6, 4.2, 4.8, 5.4
Implant Angle	0°, 12°, 24°	NA	NA	NA	24°	NA	12°	0°	NA	NA	NA	NA
Implant Material	CPTi	CPTi	CPTi	CPTi	CPTi	CPTi	CPTi	CPTi	NA	NA	NA	CPTi
Implant Surface	Grit blasted Machine collar versions available	Osseotite, NanoTite	Grit blasted	Grit blasted	Grit blasted	Grit blasted	Grit blasted	Grit blasted	NA	NA	NA	OsseoSpeed
Implant/ Abutment Interface	External hex	External hex	External hex	External hex	External hex	External hex	External hex	Tri-lobe	External hex, Internal	Internal	Internal	Internal
Implant Sterilization	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	Sterile – irradiation	NA	NA	NA	Sterile – irradiation
ABUTMENTS												
Abutment Angle	0°, 12°, 17°, 24°, 30°	0°, 15°, 17°, 25°	0°	0°	NA	0°	0°	0°	0°, 17°, 30°	0°	20°	0°, 15°, 20°, 30°
Abutment Design / Sterilization	Sterile: Cover Screw , Healing Caps, Healing Abutments, Titanium Abutments, Anatomic Abutments, Cosmetic Abutments, Compact Conical Abutments Non-sterile: Gold Abutments, Chrome Cobalt Abutments, Passive Abutments	Specific Abutments not identified in 510(k) Summary	No 510(k) Summary Available	Specific Abutments not identified in 510(k) Summary	NA	Specific Abutments not identified in 510(k) Summary	Specific Abutments not identified in 510(k) Summary	Specific Abutments not identified in 510(k) Summary	Non-Sterile Titanium Abutments	Non-Sterile Titanium Abutments	Non-Sterile TiBase Abutments and CoCr Abutments	Sterile and Non-Sterile Abutments: Cover screws, Healing Abutments, Temporary Abutments, Cast-To Abutments, Ball Abutments, Straight and Angled Abutments
Abutment Diameters	3.43, 3.5, 3.6, 4.05, 4.5, 4.6, 4.8, 5.0, 5.2, 5.5, 6.0, 6.2, 6.4, 6.5, 7.0, 7.5	Specific Abutments not identified in 510(k) Summary	No 510(k) Summary Available	Specific Abutments not identified in 510(k) Summary	NA	Specific Abutments not identified in 510(k) Summary	Specific Abutments not identified in 510(k) Summary	Specific Abutments not identified in 510(k) Summary	3.4, 4.1, 5.0	3.5, 4.0, 4.5, 5.0 6.0	4.1	3.0, 3.6, 4.2, 4.8, 5.4
Surface Treatment	Smooth, Grooved	NA	NA	NA	NA	Smooth, Grooved	Smooth	NA	NA	NA	Smooth	NA
Restoration	Single-unit or multi-unit	Single-unit or multi-unit	Single-unit or multi-unit	Single-unit or multi-unit	NA	Single-unit or multi-unit	Multi-unit	Single-unit or multi-unit	Single-unit or multi-unit	Single-unit or multi-unit	Single-unit or multi-unit	Single-unit or multi-unit
Abutment Material	CPTi, Titanium alloy, Gold, CoCr	Titanium alloy	Gold alloy	Titanium alloy, Gold alloy	NA	CPTi, Titanium alloy, Gold alloy	CPTi or Titanium alloy	Titanium alloy, Gold alloy, Stainless Steel	Titanium alloy	Titanium alloy	Titanium alloy, CoCr	Titanium alloy, Gold, Zirconia, PEEK

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter, length and angle of the abutments. The subject and predicate devices are packaged in similar materials and are to be sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.