December 9, 2019

Southern Implants (Pty) Ltd
Lauranda Breytenbach
Head of Regulatory Affairs and Quality
1 Albert Road
Irene, Gauteng 0062
SOUTH AFRICA

Re: K191054
Trade/Device Name: Southern Implants MAX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 6, 2019
Received: September 10, 2019

Dear Lauranda Breytenbach:

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.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191054

Device Name
Southern Implants MAX Implant System

Indications for Use *(Describe)*
Southern Implants MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides 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.

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
Southern Implants MAX Implant System
Southern Implants (Pty) Ltd

December 9, 2019

K191054

ADMINISTRATIVE INFORMATION

Manufacturer Name	Southern Implants (Pty) Ltd 1 Albert Road Irene, Gauteng, 0062 South Africa Telephone +27 12 667 1046 Fax +27 12 667 1029
Official Contact	Lauranda G. Breytenbach Head of Regulatory Affairs and Quality Email: lauranda.b@southernimplants.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary name	Southern Implants MAX Implant System
Common name	Dental Implant
Classification name	Endosseous dental implant
Classification regulation	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate device is K071161

The reference devices are K163634, K070905 and K180465

INDICATIONS FOR USE STATEMENT

Southern Implants MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides 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.

SUBJECT DEVICE DESCRIPTION

This submission includes threaded root-form dental implants with an external hex, internal hex and internal tri-lobe interface and mating abutments. The implants are provided in diameters of 6, 7, 8 and 9mm and lengths of 6, 7, 9 and 11mm. Specifically:

- MAX Implants with External Hex Connection
  - Ø6 mm at lengths of 6, 7, 9, 11 mm
  - Ø7 mm at lengths of 7, 9, 11 mm
  - Ø8 mm at lengths of 7, 9, 11 mm
  - Ø9 mm at lengths of 7, 9, 11 mm
- TRIMAX Implants with Tri-lobe Connection
  - Ø7 mm at lengths of 7, 9, 11 mm
  - Ø8 mm at lengths of 7, 9, 11 mm
  - Ø9 mm at lengths of 7, 9, 11 mm
- PROMAX Implants with Internal Hex Connection
  - Ø6 mm at lengths of 7, 9, 11 mm
  - Ø7 mm at lengths of 7, 9, 11 mm
  - Ø8 mm at lengths of 7, 9, 11 mm
  - Ø9 mm at lengths of 7, 9, 11 mm

This submission also includes: Coverscrews in two diameters and implant connection interfaces; Healing Abutments in two implant connection interfaces (tri-lobe and internal hex) with lengths between 3 and 6mm and diameters between 6 and 7.8mm; Titanium Cylinder abutments for temporary restorations in two implant connection interfaces (tri-lobe and internal hex) in engaging and non-engaging configurations; Cosmetic Abutments for permanent restorations in two engaging implant connection interfaces (tri-lobe and internal hex); Gold Cylinder Abutments for permanent restorations in three implant connection interfaces (external hex, tri-lobe and internal hex) in engaging and non-engaging configurations; Passive Abutments for permanent restorations in two implant connection interfaces (tri-lobe and internal hex) in engaging and non-engaging configurations; Compact Conical abutments in an internal hex connection for multi-unit restorations; and abutment screws. The Gold Cylinder Abutments and Passive Abutments are UCLA castable abutments which interface with a plastic, burn-out sleeve used to fabricate a prosthesis that is bonded directly to the top of the abutment.

All MAX implants are manufactured from unalloyed titanium conforming to ASTM F67. The implant surface is grit blasted with varying lengths of unroughened coronal portions. The Cover Screw, Healing Abutment, Titanium Cylinder Abutment, Cosmetic Abutment and Passive Abutment are manufactured from unalloyed titanium conforming to ASTM F67. The Gold Cylinder Abutment is manufactured from a gold alloy. The Compact Conical Abutments manufactured from titanium alloy conforming to ASTM

F136. The abutment screws are manufactured from titanium alloy conforming to ASTM F136, or gold-platinum alloy. All subject device components are manufactured in the same facilities using the same materials and manufacturing processes as used for the Southern Implants devices previously cleared in K071161, K163634, K070905 and K180465.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K071161 and K180465); engineering analysis; dimensional analysis; sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 17665-1, ISO TS 17665-2; bacterial endotoxin according to USP 39-NF34; sterile barrier shelf life (referenced from K071161). Pull out tests and surface area analysis comparing the worst-case subject device to the predicate device were performed. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Southern Implants (Pty) Ltd submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed devices:
K071161, Endosseous Dental Implant, Southern Implants (Pty) Ltd
K163634, External Hex Implants, Southern Implants (Pty) Ltd
K070905, Endosseous Dental Implant, Southern Implants (Pty) Ltd
K180465, Provata Implant System, Southern Implants (Pty) Ltd

The primary predicate device is K071161.
The reference devices are K163634, K070905 and K180465

A comparison of the technological characteristics of the subject device and the primary predicate device K071161 is provided in the following table.

Comparison	**Subject device**	**Primary Predicate device**
		K071161, Endosseous Dental Implant, Southern Implants (Pty) Ltd
Indications for use statement	Southern Implants MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides 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	NSI MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides 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

	when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.	stability is achieved and with appropriate occlusal loading, to restore chewing function.
Implant Design		
Implant Diameter	6, 7, 8, 9mm	8, 9mm
Implant Length	6, 7, 9, 11mm	7, 9, 11, 13mm
Implant Platform Diameter	Ø4.5, 5.5, 5.7, 6.5, 7.5mm	Ø6.5, 7.5mm
Implant Prosthetic Diameter	Ø3.575, 4, 5, 5.575, 6, 7mm	Ø6, 7mm
Implant Interface	External hex Tri-lobe Internal Hex	External hex
Material	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Implant endosseous surface	Grit-blasted	Grit-blasted
Cover Screw		
Platform diameter	Ø5.575, 6mm	Ø7mm
Maximum diameter	Ø5.6, 6mm	Ø7mm
Material	Unalloyed titanium (ASTM F67), anodized	Unalloyed titanium (ASTM F67)
Healing Abutment		
Collar height	3, 5, 6mm	4, 5.5, 7mm
Collar diameter	6, 7, 7.8mm	8mm
Material	Unalloyed titanium (ASTM F67), anodized	Unalloyed titanium (ASTM F67)
Titanium Cylinder Abutment		
Connection configurations	Engaging (single-unit) and Non-engaging (Multi-unit)	Engaging (single-unit) and Non-engaging (Multi-unit)
Prosthesis Attachment	Cement-retained	Cement-retained
Collar height	1, 3mm	1mm
Collar diameter	6.33, 6.55mm	7.33mm
Abutment Angle	0°	0°
Abutment Material	Unalloyed titanium (ASTM F67), anodized	Unalloyed titanium (ASTM F67)
Abutment Screw Material	Titanium Alloy (ASTM F136) or Gold Alloy	Titanium Alloy (ASTM F136) or Gold Alloy
Cosmetic Abutment		
Connection configurations	Engaging	N/A
Prosthesis Attachment	Cement-retained	N/A
Collar height	Varying from 1.6mm to 2.9mm	N/A
Collar diameter	Varying from 6.86 mm to 7.92mm	N/A
Abutment Angle	0°	N/A
Abutment Material	Unalloyed titanium (ASTM F67), anodized	N/A
Abutment Screw Material	Titanium Alloy (ASTM F136) or Gold Alloy	N/A
Gold Cylinder Abutment		
Connection configurations	Engaging (single-unit) and Non-engaging (Multi-unit)	N/A
Prosthesis Attachment	Screw-retained	N/A
Collar height	0.5, 0.56, 0.64mm	N/A
Collar diameter	4.3, 6.15, 6.45, 7.15mm	N/A
Abutment Angle	0°	N/A
Abutment Material	Gold Alloy	N/A

Abutment Screw Material	Titanium Alloy (ASTM F136) or Gold Alloy	N/A
Passive Abutment		
Connection configurations	Engaging (single-unit) and Non-engaging (Multi-unit)	Engaging (single-unit) and Non-engaging (Multi-unit)
Prosthesis Attachment	Screw-retained	Screw-retained
Collar height	0.3, 0.4mm	0.6mm
Collar diameter	5, 5.7, 6mm	7.2mm
Abutment Angle	0°	0°
Abutment Material	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Abutment Screw Material	Titanium Alloy (ASTM F136) or Gold Alloy	Titanium Alloy (ASTM F136) or Gold Alloy
Compact Conical Abutment		
Connection configurations	Non-engaging (Multi-unit)	N/A
Prosthesis Attachment	Screw-retained	N/A
Collar height	1, 3, 5mm	N/A
Collar diameter	6mm	N/A
Abutment Angle	0°	0°
Abutment Material	Titanium Alloy (ASTM F136) with TiN coating	N/A
Abutment Screw Material	Titanium Alloy (ASTM F136) or Gold Alloy	N/A

The Indications for Use Statement for the subject device is the same as that of the primary predicate device K071161, except for the names of the devices.

The primary predicate device K071161 is for substantial equivalence of the subject device implant design. The subject device implants have the identical design as the implants in K071161 with the exception of the diameter 6mm and 7mm implants, the length 6mm implant, the configuration of the implant where the implant surface is not roughened in the coronal 3mm of the implant body and the addition of a tri-lobe and internal hex connection system. The reference device K163634 is for substantial equivalence of the subject device diameter 6mm implant, the subject device length 6mm implant and the subject device with the unroughened coronal 3mm implant body. The reference device K070905 is for substantial equivalence of the subject device tri-lobe connection. The reference device K180465 is for substantial equivalence of the subject device internal hex connection.

The primary predicate device K071161 is for substantial evidence of the subject device Cover Screw, Healing Abutment, Titanium Cylinder, Titanium Abutment, Passive Abutment and Compact Conical Abutment designs.

The reference device K163634 is for substantial equivalence of the subject device Cosmetic Abutment and Gold Cylinder Abutment.

The reference device K163634 is for substantial equivalence of the subject device Coverscrew platform diameter, maximum diameter and material with anodizing; Healing Abutment collar height, collar diameter and material with anodizing; Titanium Cylinder Abutment collar height, collar diameter and material with anodizing; Cosmetic Abutment Cylinder connection configuration, prosthesis attachment, collar height, collar diameter and material; Gold Cylinder Abutment connection configuration, prosthesis attachment, collar height, collar diameter and material; Passive Abutment collar height and collar

diameter; Compact Conical Abutment connection configuration, prosthesis attachment, collar height and collar diameter.

The reference device K180465 is for substantial equivalence of the subject device Cosmetic Abutment material with anodizing; Passive Abutment collar height; Compact Conical Abutment material with TiN coating.

The subject device and the predicate and reference devices all incorporate the same materials and encompass similar ranges of dimensions. The surface treatment applied to the endosseous threads of the subject device implants is identical to that cleared in K071161. All subject device components are for single-patient, single-use, and all are provided sterile except for the subject device Gold Cylinder abutments and Passive Abutments, which are to be moist heat sterilized. Similarly, the components cleared in K071161 and K163634 are for single patient, single-use and are provided sterile except for the Gold Cylinder abutments and Passive Abutments, which are to be moist heat sterilized.
Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are identical in formulation, processing, component interactions, and storage conditions to the primary predicate device K071161 and reference devices K163634 and K180465.

In support of substantial equivalence in terms of mechanical performance, engineering analysis and dimensional analysis was performed and demonstrated fatigue performance of the subject device to be substantially equivalent to that of the predicate device K071161and reference devices K163634 and K180465. Pullout tests and surface area analysis demonstrated that the subject device is substantially equivalent to the reference device K163634.

CONCLUSION

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

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