November 14, 2018

Southern Implants (Pty) Ltd
% Kevin Thomas, PhD
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K181850
Trade/Device Name: Inversa Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 21, 2018
Received: August 22, 2018

Dear Kevin Thomas, PhD:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

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)*

K181850

Device Name

Inversa Implants

Indications for Use *(Describe)*

Inversa 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. Inversa 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K181850
Inversa Implants
Southern Implants (Pty) Ltd.
November 14, 2018

ADMINISTRATIVE INFORMATION

Manufacturer Name	Southern Implants (Pty) Ltd. 1 Albert Road Irene, Gauteng, South Africa 0062 Telephone: + 27 12 667 1046 Fax: + 27 12 667 1029
Official Contact	Lauranda Breytenbach Regulatory Affairs and Quality
Representative/Consultant	Kevin A. Thomas, PhD 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: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

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

PREDICATE DEVICE INFORMATION

Primary Predicate
K163634, External Hex Implants, Southern Implants (Pty) Ltd.

Reference Devices
K163060, Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd.
K030463, The Maestro System™ 7 mm & 10.5 Endosseous Implants, BioHorizons Implant Systems, Inc.
K003620, NSI Hexed and Non-Hexed Implant System, NSI
K053478, Endosseous Dental Implant System, Northern Implants, LLC
K070841, Endosseous Dental Implant System, Southern Implants, Inc.
K093562, Zygomatic Implant System, Southern Implants, Inc.

INDICATIONS FOR USE STATEMENT

Inversa 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. Inversa Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

SUBJECT DEVICE DESCRIPTION

Inversa implants are fully threaded, tapered, root-form dental implants with a design feature known as body shift, where the body design of the implant has a narrow, straight coronal portion with an increased maximum diameter midway down the length of the implant tapering toward the apex. The body of the implant includes two thread types (square and V-shaped) that transition in the middle of the implant body. Inversa implants have a platform that is inclined 12° to the long axis of the implant. Inversa Implants are made of unalloyed titanium and provided in two connection types (External Hex and Deep Conical).

External Hex Inversa implants are provided in three sizes: coronal diameter 3.5 mm with maximum apical diameter 4.5 mm; coronal diameter 3.5 mm with maximum apical diameter 5.0 mm; and coronal diameter 4.2 mm with maximum apical diameter 5.0 mm. Each size of the External Hex Inversa implant is provided in four lengths (11.5, 13, 15, and 18 mm).

Deep Conical Inversa implants are provided in three sizes: coronal diameter 3.6 mm with maximum apical diameter 4.5 mm; coronal diameter 3.6 mm with maximum apical diameter 5.0 mm; and coronal diameter 4.0 mm with maximum apical diameter 5.0 mm. Each size of the Deep Conical Inversa implant is provided in four lengths (11.5, 13, 15, and 18 mm).

Inversa implants are made from unalloyed titanium conforming to ASTM F67.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: sterilization validation according to ISO 11137-1 and ISO 11137-2 (referenced from K163634 and K163060); biocompatibility evaluation according to ISO 10993-1 (referenced from K163634 and K163060); bacterial endotoxin testing in accordance with USP 40-NF 35*;* sterile barrier shelf life (referenced from K163634); dynamic compression-bending testing according to ISO 14801, and insertion torque testing. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

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 legally marketed predicate devices.

The subject device is substantially equivalent to the primary predicate device K163634 in intended use, indications for use, material, surface, design, and function. Differences in the design features between the subject device and the primary predicate device K163634 are addressed by comparison to the reference devices as listed below.

The Indications for Use Statement for the subject device is the same as that of the primary predicate device K163634, except for the names of the devices.

The body diameter sizes for the subject device External Hex Inversa implants are substantially equivalent to the range of body diameters of the primary predicate device K163634. The body diameter sizes for the subject device Deep Conical Inversa implants are substantially equivalent to the range of body diameters of the reference device K163360. The body shift design feature is not included in the primary predicate or identified reference devices; however, the combined max/min dimensions of platform and body for any design of the submission device is within the dimension envelop of the identified predicates.

The platform diameter sizes for the subject device External Hex Inversa implants are substantially equivalent to the range of platform diameters of the primary predicate device K163634. The platform diameter size for the subject device Deep Conical Inversa implants is the same as a platform diameter size of the reference device K163360.

The implant lengths for the subject device External Hex Inversa the Deep Conical Inversa implants are substantially equivalent to the range of lengths of the primary predicate device K163634.

All subject device implants have the identical platform orientation (12° to the long axis of the implant) as the primary predicate device K163634.

The subject device External Hex Inversa implants have the identical implant-abutment connection as the primary predicate device K163634. The subject device Deep Conical Inversa implants have the identical implant-abutment connection as the reference device K163060.

All subject device implants have a thread design that includes a V-shaped design that is identical to the threads of the primary predicate device K163634. All subject device implants also have a square thread design (in the coronal aspect) that is substantially equivalent to the threads of the reference device K030463.

All subject device implants are manufactured from unalloyed titanium that is identical to the primary predicate device K163634. The surface treatment applied to the endosseous threads of the subject device implants also is identical to that cleared in the primary predicate device K163634.

The subject device implants are compatible with abutments and abutment screws cleared in the primary predicate K163436 and in the reference device K163060. The reference devices K003620, K053478, K070841, and K093562 are included in this summary to reference additional abutments and abutment screws that are compatible with the subject device.

The subject device and the predicate devices all incorporate the same materials and encompass similar ranges of dimensions. All subject device components are for single-patient, single-use, and all are provided sterile.

A comparison of the technological characteristics for the subject device, the primary predicate device, and the reference devices K163060 and K030463 is provided in the following table.

Comparison of Technological Characteristics

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device
	K181850 Inversa Implants Southern Implants (Pty) Ltd.	K163634 External Hex Implants Southern Implants (Pty) Ltd.	K163060 Deep Conical (DC) Implants and Accessories Southern Implants (Pty) Ltd.	K030463 The Maestro System™ 7 mm & 10.5 Endosseous Implants BioHorizons Implant Systems, Inc.
Indications for Use Statement	Inversa 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. Inversa Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.	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.	Southern Implants 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, • immediate loading in all indications, except in single tooth situations on implants shorter than 8mm 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 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors.	The Maestro System™ endosseous implants may be used in the mandible and maxilla for use as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and dental retention.
Product Codes	DZE	DZE, NHA	DZE, NHA	DZE
Implant Design				
Implant Body Diameter (Ø), mm		3.25, 3.75, 4.0, 4.7, 5.0, 5.7, 6.0	3.0, 3.5, 4.0, 5.0	3.5, 4, 5
Coronal Ø / Apical Ø (max)	Ex Hex 3.5 / 4.5 3.5 / 5.0 4.2 / 5.0	n/a	n/a	n/a
Coronal Ø / Apical Ø (max)	Deep Conical 3.6 / 4.5 3.6 / 5.0 4.0 / 5.0	n/a	n/a	n/a
Implant Platform Ø, mm	Ex Hex 3.45, 3.77, 4.07 Deep Conical 3.1	3.43, 4.07, 5.0, 6.0	3.1, 3.5, 4.0, 5.0	3.5, 4, 5
Implant Lengths, mm	Ex Hex 11.5, 13, 15, 18 Deep Conical 11.5, 13, 15, 18	6, 7, 8.5, 10, 11.5, 13, 15,18, 20	6, 8, 9, 11, 13, 15	7, 10.5
Platform Incline	12°	0°, 12°, 24°	0°, 12°	0°
Implant Interface	External Hex Internal Conical	External Hex	Internal Conical	External Hex
Thread design	Square and V-Shape	V-Shape	V-Shape	Square
Material				
Implant	Unalloyed Titanium	Unalloyed Titanium	Unalloyed Titanium	Unalloyed Titanium
Surface	Grit Blasted	Grit Blasted	Grit Blasted	RBM, HA

CONCLUSION

The subject device and the primary predicate device and the reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject devices are packaged in materials and are sterilized using methods that are identical to the primary predicate device K163634. The data included in this submission demonstrate substantial equivalence to the primary predicate and reference devices listed above.