



February 27, 2018

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

Re: K173343

Trade/Device Name: Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 25, 2018
Received: January 26, 2018

Dear Kevin Thomas:

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.

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.

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

Indications for Use

510(k) Number (if known)

K173343

Device Name

Zygomatic Implant System

Indications for Use (Describe)

Southern Implants Zygomatic System Standard implants, Zygan (narrow apex) implants, and Oncology implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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 – K173343
Zygomatic Implant System
Southern Implants (Pty) Ltd
February 27, 2018

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Zygomatic Implant System
Common Name	Dental implant
Classification Name	Endosseous dental implant
Classification Regulation	21 CFR 872.3640, Class II
Primary Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate device is K093562. The reference devices are K151909, K070841, K053478, and K141777.

INDICATIONS FOR USE STATEMENT

Southern Implants Zygomatic System Standard implants, Zygan (narrow apex) implants, and Oncology implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

This submission includes fully threaded and partially threaded root-form dental implants and mating abutments designed for placement into the zygomatic bone. All implants are provided with an external hexagon abutment interface angled 55° at the head of the implant. The implants are provided in three designs: Standard implant, fully threaded, diameter 4.3 mm (coronal) tapering to 3.8 mm (apical), in lengths of 30 mm and 57.5 mm; Zygan implant, partially threaded, diameter 4.3 mm (coronal) tapering to 3.4 mm (apical), in lengths from 30 mm to 57.5 mm; and Oncology implant, partially threaded diameter 4.3 mm (coronal) tapering to 3.8 mm (apical), in lengths from 30 mm to 47.5 mm.

This submission includes additional designs of Compact Conical Abutments (gingival heights 2, 3, 4, and 5.5 mm) for use with any of the implants. This submission also includes a Titanium Cylinder Abutment, for use with the Compact Conical Abutments, with a collar (gingival) height of 5 mm, and a prosthetic platform diameter of 3.4 mm. All subject device abutments are for support of screw-retained overdenture prosthetic restorations.

All subject device implants are manufactured from unalloyed titanium conforming to ASTM F67. The threaded portions of the implants have the identical aluminum oxide grit-blasted surface as the implants cleared in K093562. The subject device Compact Conical Abutments are manufactured from titanium alloy conforming to ASTM F136. The subject device Titanium Cylinder Abutment is manufactured from unalloyed titanium conforming to ASTM F67. All of the subject device components are manufactured in the same facilities using the same manufacturing processes as used for the previously cleared predicate devices in K093562 and K070841.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K093562 and K070841), engineering analysis, dimensional analysis, sterilization validation testing according to ISO 17665-1, ISO TS 17665-2, and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. The Limulus Amebocyte Lysate (LAL) test for detection and quantitation of bacterial endotoxin was conducted in accordance with USP 39-NF 34 <85> *Bacterial Endotoxin Test, using the kinetic chromogenic test method*. Clinical data referenced in this submission to support the oncology implant design included the retrospective results from 40 implants (in 20 subjects) demonstrating 100% implant success and no soft tissue complications at up to 96 months [Boyes-Varley JG, et al., *Int J Prosthodont* 2007; 20:521-531].

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:

K093562, Zygomatic Implant System, Southern Implants, Inc.;

K151909, Noris Medical Zygomatic Dental Implant System, Noris Medical Ltd.;

K070841, Endosseous Dental Implant System, Southern Implants, Inc.;

K053478, Endosseous Dental Implant System, Northern Implants, LLC; and

K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA.

A comparison of the technological characteristics of the subject device and the primary predicate device K093562 is provided in the following table.

Comparison	Subject Device	Primary Predicate Device
	Zygomatic Implant System Southern Implants (Pty) Ltd	K093562 Zygomatic Implant System Southern Implants, Inc.
Indications for Use Statement	Southern Implants Zygomatic System Standard implants, Zygan (narrow apex) implants, and Oncology implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae.
Implants		
Design	Fully and partially threaded root-form implants for placement into the zygoma	Fully threaded root-form implants for placement into the zygoma
Platform Ø	4.05 mm	4.05 mm
Implant Ø	Standard implant: 4.3 mm (coronal) taper to 3.8 mm (apical) Zygan implant: 4.3 mm (coronal) taper to 3.4 mm (apical) Oncology implant: 4.3 mm (coronal) taper to 3.8 mm (apical)	Standard implant: 4.3 mm (coronal) taper to 3.8 mm (apical)
Implant Lengths	Standard implant: 30 mm, 57.5 mm Zygan implant: 30 mm – 57.5 mm Oncology Implant: 27.5 mm – 47.5 mm	Standard implant: 35 mm – 55 mm
Threaded Lengths	Standard implant: Fully threaded Zygan implant: 6 mm coronal + 15 mm apical Oncology implant: 20 mm (apical only)	Standard implant: Fully threaded
Implant body-abutment connection angle	55°	55°
Abutments		
Design	One-piece, compact conical design	One-piece, compact conical design
Implant Interface	External hex; 55° angulation at head of implant	External hex; 55° angulation at head of implant
Gingival Height	2.0 mm – 5.5 mm	1 mm
Abutment Angle	0° (straight)	0° (straight)
Prosthesis Attachment	Screw-retained, multi-unit	Screw-retained, multi-unit
Materials		
Implants	Unalloyed titanium, ASTM F67	Unalloyed titanium, ASTM F67
Abutments	Unalloyed titanium, ASTM F67; Titanium alloy, ASTM F136	Unalloyed titanium, ASTM F67; Titanium alloy, ASTM F136

The Indications for Use Statements for the subject device and the primary predicate device K093562 are similar with the subject device statement including the additional Zygan and Oncology implants. The slight differences in wording between the Indications for Use Statements for the subject device and the primary predicate device do not affect the intended use as dental implants placed into the zygoma for rehabilitation of the edentulous maxilla.

The primary predicate device K093562 is for substantial equivalence of the subject device implant designs. The subject device Standard implants have the identical design as implants in K093562 except

for the additional lengths. The subject device Zygan implants have a design that is substantially equivalent design to implants in K093562, with the differences being the non-threaded region (starting 6 mm below the head of the implant), the diameter tapering to 3.4 mm at the apex (versus 3.8 mm for Standard implants), and the range of implant lengths. Similarly, the subject device Oncology implants have a design that is substantially equivalent to implants in K093562, with the differences being the non-threaded region starting below the head of the implant, and the range of implant lengths.

The reference device K151909 is for substantial equivalence of the subject device Oncology implant design. The implants cleared in K151909 and the subject device Oncology implants both have a non-threaded region starting at the coronal end (K151909) or just below the implant head (subject device), and a threaded region that tapers to the apex. The reference device K151909 also is for the range of implant lengths.

These differences in design between the subject devices and primary predicate devices were accounted for by including additional instructions in the labeling; therefore, the differences do not impact safety and effectiveness.

The reference device K070841 is for substantial equivalence of the subject device Compact Conical Abutment design. The subject device Compact Conical Abutments have the identical design as components cleared in K070841, with the only difference being additional sizes of gingival height.

The reference device K053478 is for substantial equivalence of the subject device Titanium Abutment design. The subject device Titanium Abutment has the identical design as components cleared in K053478, with the only difference being a change in gingival height.

The reference device K141777 is for substantial equivalence of the range of implant lengths, and for substantial equivalence of mechanical performance discussed below.

The subject device and the predicate devices all incorporate the same materials and encompass similar ranges of dimensions. The surface treatment applied to the threads of the subject device implants is identical to that cleared in K093562. The subject device and all predicate devices are provided sterile for single-patient, single-use.

The subject device implants are packaged preassembled with a titanium fixture mount. The fixture mount is made from the same unalloyed titanium as the implant. The implant-fixture mount assembly is attached to a stainless steel clip within a polyethylene terephthalate (PET) thermoformed tray, and sealed with a Tyvek® lid. The actual implant does not have any contact with the packaging material. The thermoformed tray with Tyvek® lid forms the primary sterile barrier and is placed in a PET box. The product label is placed on the Tyvek® lid. The outer box is sealed with an address label and a product description label. For the predicate device K093562, the sterile barrier is provided by the same packaging, a PET tray (blister) sealed with a Tyvek® Lid. The difference between the subject device packaging and the predicate device K093562 packaging is in the additional packaging of the implant and mount within a rigid plastic cylinder which is placed in the PET tray and sealed with the Tyvek® lid. For both the subject device and the predicate device, the primary sterile barrier is placed in a clear rigid PET box, which does not provide an additional sterile barrier but functions to protect the tray/Tyvek® lid package. The change in packaging has been addressed by specific labeling precautions, with images, for packaging handling and removal of the device into the surgical field, in order to maintain sterility of the device

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the materials being identical in formulation, processing, component interactions, and storage conditions to the predicate devices in K093562 and K070841.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing according to ISO 14801 was performed. Dynamic testing was performed on the worst-case subject device constructs. The results from the testing demonstrated fatigue performance substantially equivalent to that of the reference device K141777.

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 the predicate 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 devices are packaged in similar materials and sterilized using similar methods.

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