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

September 6, 2018

Re: K180465
Trade/Device Name: Provata Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 24, 2018
Received: July 25, 2018

Dear Kevin A. 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,

forTina 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)*

K180465

Device Name

Provata Implant System

Indications for Use *(Describe)*

The Provata Implant System is 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. The Provata Implant System is 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

K180465

Provata Implant System

Southern Implants (Pty) Ltd

September 4, 2018

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
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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	Provata Implant System
Common Name	Dental implant and abutment
Classification Name	Endosseous Dental Implant
Classification Regulation	21 CFR 872.3640
Device Class	Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate:

K163634, External Hex Implants, Southern Implants (Pty) Ltd

The reference devices are:

K040807, MIS Dental Implant System, MIS-Implant Technologies Limited
K070905, Endosseous Dental Implant System, Southern Implants, Inc.
K053478, Endosseous Dental Implant System, Northern Implants, LLC
K163060, Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd

INDICATIONS FOR USE STATEMENT

The Provata Implant System is 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. The Provata Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

SUBJECT DEVICE DESCRIPTION

This submission includes threaded root-form dental implants with an internal hexagon interface and mating abutments. The implants are provided in two designs: Straight and Co-Axis (prosthetic platform inclined 12° from orthogonal to the long axis of the implant). The Straight and Co-Axis implants are each provided in two diameters, 4.0 mm (actual major diameter 4.07 mm tapering to 2.6 mm), and 4.7 mm (actual major diameter 4.70 mm tapering to 3.13 mm), in one prosthetic diameter (3.575 mm), and in overall lengths of 8.5, 10, 11.5, 13, 15, 18 mm. The Co-Axis implants are to be used with straight abutments only.

This submission also includes: a Cover Screw (one design/size); Healing Abutments in three diameters (3.7, 4.5, and 5.5 mm) each in three gingival heights (3, 4, and 6 mm); Titanium Cylinder Abutments for temporary restorations in one size and two designs (engaging and non-engaging); Cosmetic Abutments in straight (0°), 12°, and 24° angled engaging designs for single-unit restorations; Passive Abutments with a plastic burn-out component, in one size and two designs (engaging and non-engaging); Compact Conical Abutments in straight (0°), 20°, and 30° angled designs for multi-unit restorations; and abutment screws.

All Provata implants are manufactured from unalloyed titanium conforming to ASTM F67, with a smooth machined collar. The remainder of the implant (the entire endosseous threaded surface) is grit-blasted. The subject device implant material and surface is identical to the implants cleared in K163634. The Cover Screw and all abutments (except Compact Conical) are manufactured from unalloyed titanium conforming to ASTM F67. The Compact Conical Abutments are 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 K163634 and K163060.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K163634 and K163060); 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 K163634); and static and dynamic compression-bending according to ISO 14801. 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:

K163634, External Hex Implants, Southern Implants (Pty) Ltd
K040807, MIS Dental Implant System, MIS-Implant Technologies Limited
K070905, Endosseous Dental Implant System, Southern Implants, Inc.
K053478, Endosseous Dental Implant System, Northern Implants, LLC
K163060, Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd

The primary predicate device is K163634.
The reference devices are K040807, K070905, K053478, and K163060.

A comparison of the technological characteristics of the subject device and the primary predicate device K163634 is provided in the following table.

Comparison	**Subject Device** K180465 Provata Implant System Southern Implants (Pty) Ltd	**Primary Predicate Device** K163634 External Hex Implants Southern Implants (Pty)
Indications for Use Statement	The Provata Implant System is 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. The Provata Implant System is 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.
Implant Design		
Implant Diameter	4.07 mm, 4.7 mm	4.07 mm, 4.7 mm
Implant Length	8.5, 10, 11.5, 13, 15, 18 mm	8.5, 10, 11.5, 13, 15, 18 mm
Platform Angle, Relative to orthogonal to implant long axis	0° and angled 12° (inclined)	0° and angled 12° (inclined)
Implant Platform Diameter	3.87 mm, 3.75 mm	3.43 mm, 4.07 mm, 5.0 mm
Implant Prosthetic Diameter	3.575 mm	3.43 mm, 4.07 mm, 5.0 mm
Implant Interface	Internal Hex	External Hex
Material	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Implant endosseous surface	Grit-blasted	Grit-blasted
Cover Screw		
Platform diameter	3.575 mm	3.5 mm, 5.0 mm
Maximum diameter	3.61 mm	3.5 mm, 5.35 mm
Material	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Healing Abutment		
Collar height	3, 4, 6 mm	2.2, 3, 4, 5, 6, 8 mm
Collar diameter	3.7, 4.5, 5.5 mm	3.6, 4.5, 5.5, 6.5, 7.5 mm
Material	Unalloyed titanium (ASTM F67)	Unalloyed titanium (ASTM F67)
Titanium Cylinder Abutment		
Connection configurations	Engaging and non-engaging; Single-unit and multi-unit	Engaging and non-engaging; Single-unit and multi-unit
Prosthesis Attachment	Cement-retained	Cement-retained
Collar height	2 mm	1 mm, 5 mm
Collar diameter	4.0 mm	4.3 mm, 5 mm, 6 mm
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

Comparison	Subject Device K180465 Provata Implant System Southern Implants (Pty) Ltd	Primary Predicate Device K163634 External Hex Implants Southern Implants (Pty)
Cosmetic Abutment		
Connection configurations	Engaging; Single-unit	Engaging; Single-unit
Prosthesis Attachment	Cement-retained	Cement-retained
Collar height	Varying from 1.6 mm to 2.9 mm	Varying from 1.6 mm to 2.9 mm
Collar diameter	Varying from 4.68 mm to 5.25 mm	Varying from 5 mm to 7.5 mm
Abutment Angle	0°, 12°, and 24°	0°, 12°, and 24°
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
Passive Abutment		
Connection configurations	Engaging and non-engaging; Single-unit and multi-unit	Engaging and non-engaging; Single-unit and multi-unit
Prosthesis Attachment	Screw-retained	Screw-retained
Collar height	0.4 mm	0.4 mm
Collar diameter	3.61 mm	3.43, 4.07, 5.0, 6.0 mm
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	0°: Non-engaging; Multi-unit 20° and 30°: Engaging; Multi-unit	0°: Non-engaging; Multi-unit 17° and 30°: Engaging; Multi-unit
Prosthesis Attachment	Screw-retained	Screw-retained
Collar height	0°: 1, 3, 5 mm 20°: 1.21 mm – 2.85 mm 30°: 1.21 mm – 2.85 mm	0°: 1.5, 2, 3, 4, 5.5 mm 17°: 1.5 mm – 2.9 mm 30°: 1.3 mm – 3.7 mm
Collar diameter	4.8 mm	4.8 mm, 6.0 mm
Abutment Angle	0°, 20°, 30°	0°, 17°, and 30°
Abutment Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)
Abutment Screw Material	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)

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 primary predicate device K163634 is for substantial equivalence of the subject device implant design. The subject device implants have the identical design as implants in K163634 with the exception of the internal connection interface. The reference device K040807 is for substantial equivalence of the subject device internal connection interface. The implants cleared in K040807 also have the same range of implant diameter, the same range of implant, and the same material as the subject device implants.

The primary predicate device K163634 also is for substantial equivalence of the subject device Cover Screw, Healing Abutment, Titanium Cylinder Abutment, Cosmetic Abutment, Passive Abutment, and Compact Conical Abutment designs.

The reference device K070905 is for substantial equivalence of the subject device Cover Screw material and internal connection; Healing Abutment collar height, collar diameter, and material; Titanium Cylinder connection and material with anodization; and Cosmetic Abutment connection, collar height, and material.

The reference device K053478 is for substantial equivalence of the subject device Passive Abutments internal connection and titanium alloy material.

The subject device Compact Conical Abutment has the identical TiN coating on Ti-6Al-4V alloy as overdenture abutments cleared in the reference device K163060.

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 K163634. All subject device components are for single-patient, single-use, and all are provided sterile except for the subject device Passive Abutments, which are to be moist heat sterilized. Similarly, the components cleared in K163634 are for single-patient, single-use and are provided sterile except for the 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 K163634 and reference device K163060.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing was performed according to ISO 14801. The results from the testing demonstrated fatigue performance of the subject device to be substantially equivalent to that of the predicate 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.