March 6, 2023

Southern Implants (pty) Ltd
Leith Cumming
Acting Head of Regulatory Affairs and Quality
1 Albert Rd.
Irene, Gauteng 0062
SOUTH AFRICA

Re: K222457
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, PNP
Dated: February 1, 2023
Received: February 2, 2023

Dear Leith Cumming:

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222457

Device Name
Provata Implant System

Indications for Use *(Describe)*

Indications for Use for the Provata Implants:
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. The intended use for the Ø3.30 Provata implants is limited to replacement of maxillary and mandibular lateral and central incisors. The 12° angled Co-Axis Provata Implants are intended to only be used with straight abutments.

Indications for Use for the TIB Abutments:
The TIB Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: Scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Indications for Use for the Conventional Abutments and Prosthetic Screws:
The Conventional Abutments and Prosthetic Screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.

Indications for Use for the PEEK Temporary Abutments:
The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Indications for Use for the Temporary Titanium Abutments:
The Southern Implants Temporary Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

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

Provata Implant System

Southern Implants (Pty) Ltd

March 6, 2023

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	Leith C. Cumming Acting Head of Regulatory Affairs and Quality Email: leith.c@southernimplants.com

DEVICE NAME AND CLASSIFICATION

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

PREDICATE DEVICE INFORMATION

Primary predicate devices:

K180282, MIS Internal Hex Dental Implant System, MIS Implants Technologies Ltd.

Reference devices:

K163634, External Hex Implants, Southern Implants (Pty) Ltd.
K180465, Provata Implant System, Southern Implants (Pty) Ltd.
K191250, Southern Implants PEEK abutments, Southern Implants (Pty) Ltd.
K193084, TIB Abutment System, Southern Implants (Pty) Ltd.
K151455, 3Shape Abutment Designer
K130991, SageMax NexxZr Zirconia
K130436, Ivoclar Vivadent Multilink Hybrid abutment cement

INDICATIONS FOR USE STATEMENT

Indications for Use for the Provata Implants:

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. The intended use for the Ø3.30 Provata implants is limited to replacement of maxillary and mandibular lateral and central incisors. The 12° angled Co-Axis Provata Implants are intended to only be used with straight abutments.

Indications for Use for the TIB Abutments:
The TIB Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: Scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Indications for Use for the Conventional Abutments and Prosthetic Screws:
The Conventional Abutments and Prosthetic Screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.

Indications for Use for the PEEK Temporary Abutments:
The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Indications for Use for the Temporary Titanium Abutments:
The Southern Implants Temporary Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

SUBJECT DEVICE DESCRIPTION

This submission includes fully threaded root-form dental implants with an internal hexagon interface and mating abutments. The implants are provided in two diameters: Ø3.30 and Ø4.07 mm. The Ø3.30 implants are provided in two designs: Straight and Co-Axis (prosthetic platform inclined 12° from orthogonal to the long axis of the implant). Both the Straight and Co-Axis versions are available in fully roughened and 3 mm machined coronal section configurations. The Ø3.30 Straight and Co-Axis implants are each provided in in one prosthetic diameter (2.90 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.

The Ø4.07 implants subject to this submission are provided in length 6.4mm and as Straight (0°) implants only. The Ø4.07 implants are provided with a 3.575 mm prosthetic diameter and are available in fully roughened and 2 mm machined coronal section configurations.

This submission also includes: a Cover Screw (one design/size); Healing Abutments in two diameters (3.5 and 4.5 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); Passive Abutments with a plastic burn-out component, in one size and two designs (engaging and non-engaging); PEEK Abutments for temporary restorations in one size and two designs (engaging and non-engaging); Compact Conical Abutments in straight (0°) and 20°, angled design for multi-unit restorations; Narrow TIB Abutment Bases (engaging); and abutment screws.

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, limited to a straight (0°) restoration.

The Narrow and Compact Conical TIB Abutment bases are two-piece abutment designs, consisting standard premanufactured titanium alloy abutments for supporting a hybrid/crown dental restoration and mesostructure (SageMaxx Zirconia) bonded with cement (Ivoclar Vivadent Multilink Hybrid cement). The dental laboratory is to fabricate the mesostructure restoration by CAD/CAM technique out of zirconia. The TIB abutment base then serves as the interface between the endosseous implant and the Zirconia restoration. The TIB Abutment Base is designed to support the restoration on an endosseous implant in order to restore chewing function for the patient. The mesostructured restoration is a CAD/CAM designed prosthesis milled out of Zirconia (SageMaxx Zirconia), which is designed to fit the abutment base in order to restore chewing function for the patient. Each restoration is custom designed using 3Shape Abutment Designer Software in order to meet the requirements of each patient on a case-by-case basis. Limitations have been put in place in 3Shape Abutment Designer in order to prevent malfunctioning of the restoration and a maximum allowable angulation of 20° for the mesostructured component.

All Provata implants are manufactured from unalloyed titanium conforming to ASTM F67, with a smooth machined collar (0.6mm or extended machined surface of 2 or 3 mm). 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 and K180465. The Cover Screw and Healing Abutments are manufactured from unalloyed titanium conforming to ASTM F67. The remaining Abutments are manufactured from titanium alloy conforming to ASTM F136. The PEEK Abutments are manufactured from medical grade white Polyetheretherketone. The abutment screws are manufactured from titanium alloy conforming to ASTM F136. 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, K180465, K193084 and K191250.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility evaluations according to ISO 10993-1 (referenced from K180465, K163634, K193084 and K191250); 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-NF 34; sterile barrier shelf life (referenced from K180465, K163634 and K191250, updated by extension of sterile barrier shelf life validation); short implant comparison in terms of surface area, the bone-to-implant contact and the pull-out strength; static and dynamic compression-bending according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*, MR safety testing as per the recommendations of the FDA Guidance Document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" (ASTM F2503, ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119), software validation testing per the FDA Guidance Document for Off-The-Shelf Software Use in Medical Devices (referenced from K193084); and scanning and milling validation (referenced from K193084). No clinical data were included in this submission.

Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the 3Shape Abutment Designer Software. Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the top half component of the two-piece abutment outside of the allowable design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

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 predicate devices listed above.

For the subject device Ø3.30 Provata implant system, the primary predicate device is K180282. The reference devices are K163634 and K180465 for the Ø3.30 Provata implants and abutments (excluding the PEEK abutments and Narrow TIB Abutment Bases), K191250 for the PEEK abutments, K193084 and K151455 for the Narrow TIB Abutments, and K163634 and K180465 for the 6mm length Ø4.0 Provata implants.

A comparison of the technological characteristics of the subject devices and the predicate devices is provided in the following tables.

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	Ø3.30 Provata Implant System **Southern Implants (Pty) Ltd**	**K180282** **MIS Internal Hex Dental Implant System** **MIS Implants Technologies Ltd**	**K180465** **Provata Implant System** **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implants** **Southern Implants (Pty) Ltd**
Implant				
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. The intended use for the Ø3.30 Provata implants is limited to replacement of maxillary and mandibular lateral and central incisors. The 12° angled Co-Axis Provata Implants are intended to only be used with straight abutments.	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	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.
Product Code	DZE	DZE	DZE	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/Reference	Not applicable	Implant (general design and diameter) Internal hex connection	Implant (general design and diameter) Internal hex connection Indications for Use	Implants (general design, implant length and diameter)
Item Code	PRO300; MSC-PRO300; PRO12D300; MSC-PRO12D300	MF7-xx330 (xx indicates implant length)	PRO400; MSC-PRO400; PRO12D400; MSC-PRO12D400	IBNT; MSC-IBNT
Implant Design	Fully threaded tapered root-form dental implants	Tapered, conical shape, threaded	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants

Implant Diameter	3.30 mm	3.30 mm	4.07 mm	3.25 mm
Implant Length	8.5, 10, 11.5, 13, 15, 18 mm	10, 11.5, 13, 16 mm	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° (straight)	0° and angled 12° (inclined)	0° and angled 12° (inclined)
Implant Platform Diameter	3.10 mm for 0° implant, 3.0 mm for 12° implant	Not provided	3.87 mm	3.43 mm
Implant Prosthetic Diameter	2.90 mm	Not provided	3.575 mm	3.43 mm
Machined Collar	Regular implants: 0.6 mm MSC implants: 3 mm	None	Regular implants: 0.6 mm MSC implants: 3 mm	Regular implants: 0.6 mm MSC implants: 3 mm
Implant Interface	Internal Hex	Internal Hex	Internal Hex	External Hex
Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Titanium 6Al-4V ELI per ASTM F136	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)
Implant Endosseous Surface	Grit-blasted	Anodized, sand blasted and acid etched	Grit-blasted	Grit-blasted
How Provided				
Sterility	Provided sterile	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	10 years	5 years	5 years	5 years

	Subject Device	Reference Device
Comparison	**Conventional Abutments for Ø3.30 Provata Implant System** **Southern Implants (Pty) Ltd**	**K180465** **Provata Implant System** **Southern Implants (Pty) Ltd**
Indications for Use Statement	The Conventional Abutments and Prosthetic Screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.	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.
Product Code	NHA	NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/Reference	Not applicable	General design of Cover Screw, Healing Abutment, Passive Abutment, and Compact Conical Abutment Indications for Use
Cover Screw		
Item Code	CS-3M	CS-M
Platform diameter	2.90 mm	3.575 mm
Maximum diameter	2.94 mm	3.61 mm
Material	Unalloyed titanium (ASTM F67) Grade 4, anodized	Unalloyed titanium (ASTM F67) Grade 4
Healing Abutment		
Item Code	HA-3M	HA-M
Collar height	3, 4, 6 mm	3, 4, 6 mm
Collar diameter	3.4, 4.5 mm	3.7, 4.5, 5.5 mm
Material	Unalloyed titanium (ASTM F67) Grade 4, anodized	Unalloyed titanium (ASTM F67) Grade 4
Passive Abutment		
Item Code	PA-3EM-STC; PA-3NM-STC	PA-EM-STC; PA-NM-STC
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 mm	3.61 mm
Abutment angle	0°	0°
Abutment material	Titanium alloy (ASTM F136) Grade 5	Unalloyed titanium (ASTM F67) Grade 4
Abutment screw material	Titanium alloy (ASTM F136) Grade 5	Titanium alloy (ASTM F136) Grade 5, Or gold alloy
Compact Conical Abutment		
Item Code	MC-3M; MC-3M-20D	MC-M; MC-M-20D; MC-M-30D
Connection configurations	0°: Non-engaging; Multi-unit 20°: Engaging; Multi-unit	0°: Non-engaging; Multi-unit 20° and 30°: Engaging; Multi-unit
Prosthesis attachment	Screw-retained	Screw-retained
Collar height	0°: 1, 3, 5 mm 20°: 1.56 mm – 3.20 mm	0°: 1, 3, 5 mm 20°: 1.21 mm – 2.85 mm 30°: 0.61 mm – 3.01 mm
Collar diameter	4.8 mm	4.8 mm
Abutment angle	0°, 20°	0°, 20°, 30°
Abutment material	Titanium alloy (ASTM F136) Grade 5, with TiN coating	Titanium alloy (ASTM F136) Grade 5, with TiN coating
Abutment screw material	Titanium alloy (ASTM F136) Grade 5	Titanium alloy (ASTM F136) Grade 5
How Provided		
Sterility	Provided sterile Cover Screws Healing Abutments Compact Conical Abutments All abutment screws Provided nonsterile Passive Abutments	Provided sterile Cover Screws Healing Abutments Compact Conical Abutments All abutment screws Provided nonsterile Passive Abutments

Sterilization	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	5 years	5 years

	Subject Device	Reference Device	Reference Device
Comparison	**Temporary Titanium Abutments for Ø3.30 Provata Implant System** **Southern Implants (Pty) Ltd**	**K180465** **Provata Implant System** **Southern Implants (Pty) Ltd**	**K191250** **Southern Implants PEEK abutments** **Southern Implants (Pty) Ltd**
Temporary Titanium Abutment			
Indications for Use Statement	The Southern Implants Temporary Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.	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.	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.
Product Code	NHA	NHA	NHA
Item Code	TC-3M; TC-3NM	TC-M; TC-NM	PKIP2H; PKIP2NH; PKC-M-2; PKC-NM-2
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.	Temporary Abutment
Reason for Predicate/Reference	Not applicable	Titanium Cylinder Abutment design	Indications for Use
Connection configurations	Engaging and non-engaging; Single-unit and multi-unit	Engaging and non-engaging; Single-unit and multi-unit	Engaging and non-engaging; Single-unit and multi-unit
Prosthesis attachment	Cement-retained	Cement-retained	Cement-retained
Collar height	2 mm	2 mm	2 mm
Collar diameter	3.5 mm	4.0 mm	3.35, 4.0 mm
Abutment angle	0°	0°	0°
Implant Connection	Internal Hex	Internal Hex	External Hex; Internal Hex
Abutment material	Titanium alloy (ASTM F136) Grade 5, anodized	Unalloyed titanium (ASTM F67) Grade 4, anodized	Polyetheretherketone (PEEK) (white)
Abutment screw material	Titanium alloy (ASTM F136) Grade 5	Titanium alloy (ASTM F136) Grade 5, Or gold alloy	Titanium alloy (ASTM F136) Grade 5, Or gold alloy
How Provided			
Sterility	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	5 years	5 years	5 years

Comparison	Subject Device	Reference Device
	PEEK Abutments for Ø3.30 Provata Implant System **Southern Implants (Pty) Ltd**	**K191250** **Southern Implants PEEK abutments** **Southern Implants (Pty) Ltd**
PEEK Abutment		
Indications for Use Statement	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.
Product Code	NHA	NHA
Item Code	PKC-3M-2; PKC-3NM-2	PKIP2H; PKIP2NH; PKC-M-2; PKC-NM-2
Intended Use	Temporary Abutment	Temporary Abutment
Reason for Predicate/Reference	Not applicable	PEEK abutment (all aspects of device design and Indications for Use)
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	2 mm
Collar diameter	3.50 mm	3.35, 4 mm
Abutment angle	0°	0°
Implant Connection	Internal Hex	External Hex; Internal Hex
Abutment material	Polyetheretherketone (PEEK) (white)	Polyetheretherketone (PEEK) (white)
Abutment screw material	Titanium alloy (ASTM F136) Grade 5	Titanium alloy (ASTM F136) Grade 5, Or gold alloy
How Provided		
Sterility	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	5 years	5 years

Comparison	Subject Device	Reference Device
	Narrow TIB Abutment Bases for Ø3.30 Provata Implant System **Southern Implants (Pty) Ltd**	**K193084** **TIB Abutment System** **Southern Implants (Pty) Ltd**
Narrow TIB Abutment Base		
Indications for Use Statement	The TIB Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: Scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	The TIB Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: Scan files from desktop scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.
Product Code	NHA, PNP	NHA, PNP
Item Code	TIBS-3M-C1.5 TIBS-3M-C3	TIB-M-C1.5 TIB-M-C3
Intended Use	Permanent abutment	Permanent abutment
Reason for Predicate/Reference	Not applicable	Abutment (general design and functioning) Software Compatibility Indications for Use
Abutment design	2 Piece – Premanufactured titanium abutment, mounted onto the implant and fixed with a screw. SageMaxx Zirconia (K130991) hybrid/crown restoration milled and bonded to the titanium abutment.	2 Piece – Premanufactured titanium abutment, mounted onto the implant and fixed with a screw. SageMaxx Zirconia (K130991) hybrid/crown restoration milled and bonded to the titanium abutment.
Collar height	1.5 or 3 mm	1.5 or 3 mm
Maximum abutment angle	20°	20°
Implant Connection	Internal Hex	Internal Hex
Post height	Minimum 4.5 mm	Minimum 4.5 mm
Abutment Restorative Platform Diameter	3.85 mm	4.50 mm
Abutment material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Abutment surface	Machined and anodized	Machined and anodized
Abutment screw material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Restoration material	Zirconia - Sage Maxx NexxZr (K130991)	Zirconia - Sage Maxx NexxZr (K130991)
CAD/CAM Design Workflow	3Shape E3 Desktop Scanner (3Shape A/S) 3Shape Abutment Designer Software	3Shape E3 Desktop Scanner (3Shape A/S) 3Shape Abutment Designer Software
CAD/CAM Manufacturing Workflow	WorkNC CAM software, Roland DWX51D milling unit	WorkNC CAM software, Roland DWX51D milling unit
Mechanical Fatigue Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801
How Provided		
Sterility	Provided non-sterile	Provided non-sterile
Usage	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	5 years	5 years

Comparison	Subject Device	Reference Device	Reference Device
	6mm Ø4.0 Provata Implant System **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implants** **Southern Implants (Pty) Ltd**	**K180465** **Provata Implant System** **Southern Implants (Pty) Ltd**
6 mm length Ø4.0 Implant			
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. The intended use for the Ø3.30 Provata implants is limited to replacement of maxillary and mandibular lateral and central incisors. The 12° angled Co-Axis Provata Implants are intended to only be used with straight abutments	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.	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.
Product Code	DZE	DZE	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/Reference	Not applicable	Implant Design Implant Length	Implant (general design and diameter) Internal hex connection Indications for Use
Item Code	PRO406; MSC-PRO406	IBT; MSC-IBT	PRO400; MSC-PRO400;
Implant Design	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants
Implant Diameter	4.07 mm	4.07 mm	4.07 mm
Implant Length	6.4 mm	6, 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°	0°	0°
Implant Platform Diameter	3.87 mm	4.07 mm	3.87 mm
Implant Prosthetic Diameter	3.575 mm	4.07 mm	3.575 mm
Machined Collar	Regular implants: 0.6 mm MSC implants: 2 mm	Regular implants: 0.6 mm MSC implants: 3 mm	Regular implants: 0.6 mm MSC implants: 2 mm
Implant Interface	Internal Hex	External Hex	Internal Hex
Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)
Implant Endosseous Surface	Grit-blasted	Grit-blasted	Grit-blasted
How Provided			
Sterility	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	10 years	5 years	5 years

The Indications for Use Statement for the subject device implants is identical to the reference device K180465, with the only difference being the indication of the Ø3.30 Provata implants limited to replacement of maxillary

and mandibular lateral and central incisors, and the additional limited use of straight abutments only for the 12° Co-Axis Provata implants. The Indications for Use Statement for the subject device is similar to the primary predicate device K180282 in terms of the limited indication for the narrow implants (Ø3.3mm and UNO implants) for replacement of mandibular central, lateral incisor and maxillary lateral incisor. The subject device thus has an indication for use significantly similar to the predicate devices. Additionally, the subject device Indications for Use statement specifies the intended use of the Narrow TIB Abutments, a statement identical to that of predicate K193084.

The primary predicate device K180282 is for substantial equivalence of the subject device Ø3.30 implant designs. The subject device implants have a similar internal hex connection and identical major diameter as implants in K180282, specifically the Narrow Platform MIS SEVEN implants. The subject device implants' indications for use is limited to the central and lateral mandibular and maxillary incisors, whereas the predicate's (K180282) indication for use excludes the maxillary central incisors. The reference device K163634 is for substantial equivalence of the subject device implant diameter, lengths (8.5 mm to 18 mm), platform angle (0° and 12°), material, machined collar, and endosseous surface. The reference device K180465 is for substantial equivalence of the subject device internal connection.

The reference device K180465 also serves as a predicate for substantial equivalence of the subject device Conventional abutment designs. The reference device K163634 is for the substantial equivalence of the subject device abutment-implant prosthetic diameter and surface treatment. The slight difference in Indications for Use statements for the Conventional Abutments and the reference device predicate K180465 does not affect the intended use of the devices, which is to provide support for crowns, bridges and overdentures in the maxilla and mandible. The slight difference in Indications for Use statement for the Conventional Abutments provides a description of the devices to differentiate them as prosthetic components being connected to endosseous dental implants, rather than being the endosseous implant.

The reference device K180465 also serves as a predicate for substantial equivalence of the subject device Temporary Titanium Abutment designs. The reference device K163634 is for the substantial equivalence of the subject device abutment-implant prosthetic diameter and surface treatment. The reference device K191250 serves as a predicate for substantial equivalence of the subject device Temporary Titanium Abutment Indications for Use.

The reference device K191250 also serves as a predicate for substantial equivalence of the subject device PEEK abutment designs and Indications for Use.

The reference device K193084 serves as a predicate for substantial equivalence of the subject device Narrow TIB Abutment Base designs and Indications for Use.

The subject device implants encompass similar ranges of dimensions as the predicate device cleared in K180282. The material, surface treatment applied to the endosseous threads of the subject device implants is identical to that cleared in K163634 and K180465. The material and surface treatment applied to the subject device abutments is identical to that of the abutments cleared in K163634, K180465, K193084 and K191250. All subject device components are for single-patient, single-use, and all are provided sterile (except the Passive Abutments and Narrow TIB Abutment Bases which are provided non-sterile identical to Passive Abutments cleared in K180465 and the TIB Abutment Bases in K193084). Similarly, the components cleared in K180282, K163634, K180465 and K191250 are for single-patient, single-use and are provided sterile (excluding the Passive Abutments and Narrow TIB Abutment Bases).

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 devices in K163634, K180465, K193084 and K191250.

In support of substantial equivalence of the Ø3.30 implants in terms of mechanical performance, dynamic compression-bending testing was performed according to ISO 14801. Dynamic testing was performed on worst-case subject device constructs. The results from the testing demonstrated fatigue performance of the subject device that exceeds its indication. To demonstrate that the subject device 6 mm length Ø4.0 implants are substantially

equivalent to a predicate short length implant (cleared in K163634) a report detailing an analysis of the comparative surface area, the comparative bone-to-implant contact and the comparative pull-out strength is provided.

CONCLUSION

The subject device and the predicate devices have a significantly similar intended use, have similar technological characteristics, and are made of the same 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.