Southern Implants (Pty) Ltd
Michelle dos Santos
Senior Design Engineer
1 Albert Road
Irene, Gauteng 0062
SOUTH AFRICA

December 1, 2023

Re: K232418
Trade/Device Name: Single Platform SP1 Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA, PNP
Dated: November 1, 2023
Received: November 2, 2023

Dear Michelle dos Santos:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K232418

Device Name
Single Platform SP1 Implant System

Indications for Use *(Describe)*

For the implants:
The Single Platform SP1 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 Single Platform SP1 Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.
The Single Platform SP1 implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

For the conventional abutment and 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.

For the Titanium Abutment Bases and Passive Abutments:
The TIB and Passive Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB and Passive 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.

For the Temporary Titanium Cylinders:
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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K232418

Single Platform SP1 Implant System

Southern Implants (Pty) Ltd

December 01, 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	Colin Saffy Head of Regulatory Affairs and Quality Email: colin.s@southernimplants.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Single Platform SP1 Implant System
Common Name	Dental implant
Classification Name	Endosseous dental implant
Classification Regulation	21 CFR 872.3640, Class II
Product Code	DZE, NHA, PNP
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate devices:

K163194, Neodent Implant System – GM Line, JJGC Industria e Comercio de Materiais Dentarios SA.

Reference devices:

K190958, Neodent Implant System – GM Helix LG, JJGC Industria e Comercio de Materiais Dentarios SA.
K163060, Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd.
K222457, Provata Implant System, Southern Implants (Pty) Ltd.
K180536, Neodent Implant System – GM Line, JJGC Industria e Comercio de Materiais Dentarios SA.
K191191, Neodent Implant System – Temporary Abutments, JJGC Industria e Comercio de Materiais Dentarios SA.
K212785, Blue Sky Bio Multi One Implant System, Blue Sky Bio Long Implant System, Blue Sky Bio PEEK temporary abutments, Blue Sky Bio, LLC.
K130991, NexxZR™ T and NexxZR™ T, Sagemax Bioceramics, Inc.
K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent, Inc.

INDICATIONS FOR USE STATEMENT

For the implants:

The Single Platform SP1 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

Single Platform SP1 Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

The Single Platform SP1 implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

For the conventional abutment and 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.

For the Titanium Abutment Bases (TIB) and Passive Abutments:
The TIB and Passive Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB and Passive 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.

For the Temporary Titanium Cylinders:
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 cone and hexagon interface and mating abutments. The implants are provided in three diameters: Ø3.5, Ø4.0 and Ø5.0 mm. The implants are provided in a straight (0° angled) configuration only, with a 3.0 mm extended machined coronal section. The implants are provided in one prosthetic diameter (2.95 mm). The Ø3.5 mm implants are provided in overall lengths of 8, 10, 11.5, 13, 16, 18 and 20 mm. The Ø4.0 mm implants are provided in overall lengths of 8, 10, 11.5, 13, 16, 18, 20, 22 and 24 mm. The Ø5.0 mm implants are provided in overall lengths of 8, 10, 11.5, 13, 16, and 18 mm.

This submission also includes: a Cover Screw, Healing Abutments in four diameters and multiple gingival heights, Titanium Cylinder Abutments for temporary restorations, Passive Abutments with a plastic burn-out component, Equator Overdenture Abutments in multiple gingival heights, Compact Conical Abutments in straight (0°) and angled (17° and 30°) designs, TIB Abutment Bases, and abutment screws.

The Passive Abutments may be restored using either traditional cast-on workflows or digital CAD/CAM workflows using milled zirconia restorations (similar use to the TIB Abutment Bases).

Using the traditional cast-on workflow, the Passive Abutments function as 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 when utilizing precious metal cast-on restorations.

Using digital CAD/CAM workflows, the TIB Abutment Bases and Passive Abutments function as two-piece abutment designs, consisting of standard premanufactured titanium alloy abutments for supporting the second half (or top-half) of the abutment, 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 Bases and Passive Abutments then serves as the interface between the endosseous implant and the Zirconia restoration. The TIB Abutment Bases and Passive Abutments are 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 Single Platform SP1 implants are manufactured from unalloyed titanium conforming to ASTM F67, with a smooth machined collar (extended machined surface of 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 K222457 and K163060. 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 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 K222457 and K163060.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence.

Non-clinical data submitted to demonstrate substantial equivalence includes: engineering analysis; dimensional analysis; sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 17665-1, ISO 17665-2; bacterial endotoxin according to USP 39-NF 34; static and dynamic compression-bending according to ISO 14801 Dentistry – Implants – Dynamic fatigue test for endosseous dental implants; scanning and milling validation for the Passive Abutments; and 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".

Non-clinical data referenced, or relied upon to demonstrate substantial equivalence includes: biocompatibility evaluations according to ISO 10993-1 (referenced from K222457 and K163060); sterile barrier shelf life (referenced from K222457); validated steam sterilization instructions per ISO 17665-1 and ISO 17665-2 (applicable to the Passive Abutments and Titanium Abutment Bases (TIB) which are provided non-sterile and intended for end-user sterilization – referenced from K193084); software validation testing as per the FDA Guidance Document for Off-The-Shelf Software Use in Medical Devices (referenced from K193084); and scanning and milling validation for the Titanium Abutment Bases (TIB) (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 (only applicable to the TIB Abutment Bases and Passive Abutments when using the digital CAD/CAM workflows for milled zirconia restoration design). 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.

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) was performed on the previously cleared devices, K222457, PROVATA Implant System. The subject devices were compared to the predicate devices. The subject devices are not worst-case Southern Implants components in terms of material, size or shape and therefore the subject devices can be considered equally MR Safe as the predicate devices.

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 Single Platform SP1 implants, the primary predicate device is K163194, and the reference devices are K190958, K163060, K222457 and K212785.

For the subject device Conventional Abutments and Prosthetic Screws for Single Platform SP1 implants, the reference devices are K163194, K163060 and K222457.

For the subject device TIB Abutment Bases and Passive Abutments for Single Platform SP1 implants, the reference devices are K222457, K180536 and K163060.

For the subject device Temporary Titanium Abutments for Single Platform SP1 implants, the reference devices are K222457 and K191191.

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	Reference Device	Reference Device
	Single Platform SP1 Implant System **Southern Implants (Pty) Ltd**	**K163194** **Neodent Implant System – GM Line** **JJGC Industria e Comercio de Materiais Dentarios SA**	**K190958** **Neodent Implant System – GM Helix LG** **JJGC Industria e Comercio de Materiais Dentarios SA**	**K163060** **Deep Conical (DC) Implants and Accessories** **Southern Implants (Pty) Ltd**	**K222457** **Provata Implant System** **Southern Implants (Pty) Ltd**	**K212785** **Blue Sky Bio Dental Implant System - BIO|MAX MULTI ONE** **Blue Sky Bio, LLC**
Implant						
Indications for Use Statement	The Single Platform SP1 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 Single Platform SP1 Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved. The Single Platform SP1 implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	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 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 03.30 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.	Blue Sky Bio Multi One Implant System is intended for surgical placement in the bone of the upper or lower jaw to provide support for prosthetic devices to restore chewing function. Implants may be used with single-stage or two-stage procedures. They can be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Multi One Implants are indicated for multi-unit restorations in splinted applications. Blue Sky Bio Multi One Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.
Product Code	DZE	DZE	DZE	DZE	DZE	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Root-form implants intended to replace natural tooth root.	Root-form implants intended to replace natural tooth root.	Bone anchored dental prosthetic	Functional and esthetic rehabilitation of the edentulous maxilla.	Root-form implants intended to replace natural tooth root.
Reason for Predicate/ Reference	Not applicable	General implant design, length and diameter Internal cone and hex connection	Implant lengths	General design and diameter Implant material and surface Sterility Sterilization Usage	Machined collar Implant material and surface Shelf-life of packaging Sterility Sterilization Usage	Implant diameter and length combination

Item Code	MSC-SP35; MSC-SP40; MSC-SP50	GM Helix	GM Helix LG	DCC35; DCC40; DCC50; DCT35; DCT40; DCT50	MSC-PRO300	BIO|MAX MULTI ONE Ø 3.25 mm Straight
Implant Design	Fully threaded tapered root-form dental implants	Threaded root-form implant with internal GM Morse taper connection with internal hex	Threaded root-form implant with internal GM Morse taper connection with internal hex	Fully threaded cylindrical and tapered root-form dental implants	Fully threaded tapered root-form dental implants	One-piece implant/abutment
Implant Diameter	3.50, 4.0 and 5.0 mm	3.50, 3.75, 4.0, 4.3 and 5.0 mm	3.75 and 4.0 mm	3.52, 4.0 and 5.0mm	3.30 mm	3.25 mm
Implant Length	For Ø3.5 implants: 8, 10, 11.5, 13, 16, 18, 20 mm For Ø4.0 implants: 8, 10, 11.5, 13, 16, 18, 20, 22, 24 mm For Ø5.0 implants: 8, 10, 11.5, 13, 16, 18 mm	8, 10, 11.5, 13, 16, 18 mm	20, 22, 25 mm	8, 9, 11, 13, 15 mm	8.5, 10, 11.5, 13, 15, 18 mm	10, 11.5, 13, 16, 18, 20 mm
Platform Angle, Relative to orthogonal to implant long axis	0° (straight)	0° (straight)	0° (straight)	0° (straight)	0° (straight)	0° (straight)
Implant Platform Diameter	For Ø3.5 implants: 3.30 mm For Ø4.0 implants: 3.80 mm For Ø5.0 implants: 4.50 mm	Not provided	Not provided	For Ø3.52 and Ø4.0 implants: 3.10 mm For Ø5.0 implants: 4.10 mm	3.10 mm	3.50 mm
Implant Prosthetic Diameter	2.95 mm	Not provided	Not provided	For Ø3.52 and Ø4.0 implants: 2.80 mm For Ø5.0 implants: 3.83 mm	2.90 mm	3.50 mm
Implant Interface	Internal Cone and Hex	GM interface, 16° Morse taper with anti-rotational features (Internal cone and hex)	GM interface, 16° Morse taper with anti-rotational features (Internal cone and hex)	Deep Conical (internal cone and double hex)	Internal Hex	One piece
Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4	Unalloyed titanium (ASTM F67) Grade 4	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Implant Endosseous Surface	Grit-blasted with a 3.0mm machined section only at coronal end	Grit-blasted and acid etched (NeoPoros and Acqua)	Grit-blasted and acid etched (NeoPoros)	Grit-blasted with a 0.3mm machined section only at coronal end	Grit-blasted with a 3.0mm machined section only at coronal end	Grit blasted and acid etched
How Provided						
Sterility	Provided sterile	Provided sterile	Provided sterile	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Not provided	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	10 years	Not provided	Not provided	5 years	10 years	Not provided

	Subject Device	Primary Predicate Device	Reference Device
Comparison	**Conventional Abutments and Prosthetic Screws for Single Platform SP1 Implant System** **Southern Implants (Pty) Ltd**	**K163194** **Neodent Implant System – GM Line** **JJGC Industria e Comercio de Materiais Dentarios SA**	**K163060** **Deep Conical (DC) Implants and Accessories** **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 Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	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.
Product Code	NHA	NHA	NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Immediate or conventional rehabilitation procedures on the maxilla or mandible.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/ Reference	Not applicable	Cover Screw Healing Abutment Compact Conical Abutment (general design and functioning)	Cover Screw Healing Abutment Compact Conical Abutment Equator Overdenture Abutment (general design and functioning)
Implant Connection	Internal Cone and Hex (SP1)	GM interface, 16° Morse taper with anti-rotational features (Internal cone and hex)	Deep Conical (internal cone and double hex)
Cover Screw			
Item Code	CS-SP	GM Cover screw	CS-DC
Platform diameter	2.95 mm	Not provided	2.35, 2.85, 3.90 mm
Maximum diameter	3.10 mm	Not provided	2.38, 2.88, 3.93 mm
Abutment material	Unalloyed titanium (ASTM F67) Grade 4	Ti-6Al-4V ELI Titanium Alloy (ASTM F136)	Unalloyed titanium (ASTM F67) Grade 4
Abutment surface	Machined	Machined and anodized	Machined and anodized
Healing Abutment			
Item Code	HA-SP	GM Healing abutment	HA-DC
Collar height	2.5, 3.5, 4.5, 5.5 mm	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm	1.8, 3.8, 5.8 mm
Collar diameter	4.5, 5.0, 5.5, 6.5 mm	3.5, 4.5, 5.5, 6.5 mm	4.5, 5.5, 6.5 mm
Abutment material	Unalloyed titanium (ASTM F67) Grade 4	Ti-6Al-4V ELI Titanium Alloy (ASTM F136)	Unalloyed titanium (ASTM F67) Grade 4
Abutment surface	Machined and anodized	Machined and anodized	Machined and anodized
Equator Overdenture Abutment			
Item Code	EQ-SP	N/A	EQ-DC
Connection configurations	Non-engaging; Multi-unit		Non-engaging; Multi-unit
Prosthesis attachment	Removable		Removable
Collar height	2.0, 4.0, 6.0 mm		2.0, 4.0, 6.0 mm
Collar diameter	4.5 mm		3.5, 4.0 mm
Abutment angle	0°		0°

Abutment material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)		Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Abutment surface	Machined with TiN coating		Machined with TiN coating
Compact Conical Abutment			
Item Code	MC-SP; MC-SP-17D; MC-SP-30D	GM Mini Conical Abutments	MC-DC
Connection configurations	0°: Non-engaging; Multi-unit 17° and 30°: Engaging; Multi-unit	0°: Non-engaging; Multi-unit 17° and 30°: Engaging; Multi-unit	Non-engaging; Multi-unit
Prosthesis attachment	Screw-retained	Screw-retained	Screw-retained
Collar height	0°: 1.5, 2.5, 3.5, 4.5 mm 17°: 1.5, 2.5, 3.5 mm (low side height) 30°: 2.5, 3.5 mm (low side height)	0°: 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm 17° and 30°: 1.5, 2.5, 3.5 mm	1.5, 3.0, 4.0, 5.0 mm
Collar diameter	4.8 mm	4.8 mm	4.8, 6.0 mm
Abutment angle	0°, 17°, 30°	0°, 17°, 30°	0°
Abutment material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V ELI Titanium Alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Abutment surface	Machined with TiN coating	Machined	Machined with TiN coating
Abutment screw material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Not provided	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
How Provided			
Sterility	Provided sterile	Sterile	Provided sterile
Sterilization	Gamma irradiation	Ethylene Oxide	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use
Shelf life of packaging	5 years	Not provided	5 years

Comparison	Subject Device **TIB Abutment Bases and Passive Abutments for Single Platform SP1 Implant System** **Southern Implants (Pty) Ltd**	Reference Device **K222457** **TIB Abutment Bases and Passive Abutments for Ø3.30 Provata Implant System** **Southern Implants (Pty) Ltd**
Indications for Use Statement	The TIB and Passive Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The TIB and Passive 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
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/ Reference	Not applicable	TIB Abutment Passive Abutment (general design and functioning) Software Compatibility
Implant Connection	Internal Cone and Hex (SP1)	Internal Hex
TIB Abutment Base		
Item Code	TIB-SP; TIB-NSP; TIB-SP-PM	TIBS-3M-C1.5 TIBS-3M-C3
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, 3.0 mm	1.5, 3.0 mm
Maximum abutment angle	20°	20°
Post height	Minimum 4.5 mm	Minimum 4.5 mm
Abutment Restorative Platform Diameter	4.50, 5.50 mm	3.85 mm
Abutment titanium base component material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Abutment surface	Machined and anodized	Machined and anodized
Abutment screw material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Passive Abutment		
Item Code	PA-SP; PA-NSP; PA-SP-PM	PA-3EM-STC; PA-3NM-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	1.0 mm	0.4 mm
Collar diameter	3.9, 5.0 mm	3 mm
Maximum abutment angle	20° for zirconia restorations (digital CAD/CAM workflows) 0° for precious metal cast-on restorations (traditional workflows)	0°
Abutment titanium base component material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Abutment surface	Machined and anodized	Machined
Abutment screw material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
CAD/CAM Process		
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
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

	Subject Device	Reference Device
Comparison	**Temporary Titanium Abutments for Single Platform SP1 Implant System** **Southern Implants (Pty) Ltd**	**K222457** **Temporary Titanium Abutments for Ø3.30 Provata Implant System** **Southern Implants (Pty) Ltd**
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 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.
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	Titanium Cylinder Abutment (general abutment design) Abutment and screw materials and surface Shelf-life of packaging Sterility status and Sterilization Method Usage
Implant Connection	Internal Cone and Hex (SP1)	Internal Hex
Titanium Cylinder Abutment		
Item Code	TC-SP; TC-NSP; TC-SP-PM	TC-3M; TC-3NM
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	1.5 mm	2.0 mm
Collar diameter	4.5, 5.5 mm	3.5 mm
Abutment angle	0°	0°
Abutment material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Abutment surface	Machined and anodized	Machined and anodized
Abutment screw material	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)	Ti-6Al-4V Titanium Grade 5 alloy (ASTM F136)
Duration of use	180 days	180 days
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

The Indications for Use Statements for the subject device implants and the reference device K222457 are similar with the subject device statement including a restriction for the longer length implants (i.e., lengths 20 – 24 mm) to be splinted in multiple-unit restorations. This restriction is similar to that of reference devices K190958 and K212785.

The Indications for Use Statements for the subject device abutments and the reference device K222457 are identical for the Conventional Abutments and Prosthetic screws, the TIB Abutment Bases, and the Temporary Titanium Abutments.

For the subject device Single Platform SP1 implants, the primary predicate device is K163194, and the reference devices are K190958, K163060, K222457 and K212785. The primary predicate device K163194 is for substantial equivalence of the subject device implant connection interface, implant diameters, implant lengths, and general designs. The subject device implants have a similar internal cone and hex connection, similar implant diameters and lengths as implants in K163194. The reference device K190958 is for substantial equivalence of the subject device implant longer lengths of 20 – 24 mm. The subject device implants' indications for use is limited to splinted multiple-unit restorations for the longer length implants (i.e., lengths 20 - 24mm) which is similar to the indications for use of reference device K190958. The subject device implants' indications for use is similar to reference device K222457, with the reference device having an additional limitation for narrow diameter implants (<Ø3.30 mm) which is not relevant to the subject device implants. The reference device K163060 is for substantial equivalence of the subject device implant material, surface, sterility, sterilization and usage. The reference devices K212785 are for substantial equivalence of the subject device implant diameter and length, specifically the Ø3.5 Single Platform SP1 implants. The reference device K222457 is for substantial equivalence of the subject device implant machined collar, and packaging shelf life.

For the subject device Conventional Abutments and Prosthetic Screws for Single Platform SP1 implants, the reference devices are K163194, K163060 and K222457. The reference device K163194 serves as a predicate for substantial equivalence of the subject device abutment connection interface, and general designs of the Cover Screw, Healing Abutments and Compact Conical Abutments. The reference devices K163060 and K222457 is for the substantial equivalence of the subject device abutment materials, surface treatment and general designs of the Cover Screw, Healing Abutments and Compact Conical Abutments. The reference device K163060 is for the substantial equivalence of the subject device abutment materials, surface treatment and general designs of the Cover Screw, Healing Abutments, Equator Overdenture Abutments and Compact Conical Abutments. -implant prosthetic diameter and surface treatment.

For the subject device TIB Abutment Bases and Passive Abutments for Single Platform SP1 implants, the reference devices are K222457, K180536 and K163060. The reference device K222457 serves as a predicate for substantial equivalence of the subject device abutment material, surface treatment, sterility, usage, software compatibility and general designs. The reference device K180536 is for the substantial equivalence of the subject device abutment connection interface and general design of the TIB Abutment Bases. The reference device K163060 is for the substantial equivalence of the subject device abutment general design of the Passive Abutments.

For the subject device Temporary Titanium Abutments for Single Platform SP1 implants, the reference devices are K222457 and K191191. The reference device K222457 serves as a predicate for substantial equivalence of the subject device abutment material, surface treatment, packaging shelf life, sterility, sterilization, usage and general design of the Temporary Titanium Abutments. The reference device K191191is for the substantial equivalence of the subject device abutment connection interface and general design of the Temporary Titanium Abutments.

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 K163060 and K222457. All subject device components are for single-patient, single-use, and all are provided sterile (except the Passive Abutments and TIB Abutment Bases which are provided non-sterile identical to Passive Abutments and TIB Abutment Bases cleared in K222457, and the Passive Abutments cleared in K163060). Similarly, the components cleared in K163060 and K222457 are for single-patient, single-use and are provided sterile (excluding the Passive Abutments and 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 predicate devices in K163060 and K222457.

In support of substantial equivalence of the Single Platform SP1 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.

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.