August 1, 2023

Southern Implants (Pty) Ltd
Colin Saffy
Head of Regulatory Affairs and Quality
1 Albert Road
Irene, Gauteng 0062
SOUTH AFRICA

Re: K230873
Trade/Device Name: Angulated Screw Channel (ASC) Solution Abutments and SI-BASE Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: June 29, 2023
Received: June 30, 2023

Dear Colin Saffy:

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)*
K230873

Device Name
Angulated Screw Channel (ASC) Solution Abutments & SI-BASE Abutments

Indications for Use *(Describe)*
The Angulated Screw Channel (ASC) Solution Abutments and SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The ASC Solution Abutments and SI-BASE Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a multi-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 intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.0 External-Hex implants, Ø3.3 PROVATA implants and Ø3.5/Ø4.0 Deep Conical implants are intended for use with a straight mesostructure component.

The intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.4 and Ø4.0 External-Hex implants, PROVATA implants and Ø3.5 and Ø4.3 TRI-NEX implants is limited to replacement of maxillary and mandibular lateral and central incisors.

The ASC Solution Abutments and SI-BASE Abutments for Compact Conical Abutments are intended for use on straight Compact Conical Abutments with a straight mesostructure component.

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.

510(k) Summary
K230873

Angulated Screw Channel (ASC) Solution and SI-BASE Abutments

Southern Implants (Pty) Ltd

July 31, 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 A. Saffy Head of Regulatory Affairs and Quality Email: colin.s@southernimplants.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary name	Angulated Screw Channel (ASC) Solution Abutments & SI-BASE Abutments
Common name	Dental Abutment
Classification name	Endosseous Dental Implant Abutment
Classification regulation	21 CFR 872.3630, Class II
Primary Product Code	NHA
Secondary Product Code	PNP
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate device is K193084
The reference predicate devices are K173706, K222457, K163634, K163060, K053478, K070905, K130991, K130436, and K151455.

INDICATIONS FOR USE STATEMENT

The Angulated Screw Channel (ASC) Solution Abutments and SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The ASC Solution Abutments and SI-BASE Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a multi-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 intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.0 External-Hex implants, Ø3.3 PROVATA implants and Ø3.5/Ø4.0 Deep Conical implants are intended for use with a straight mesostructure component.

The intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.4 and Ø4.0 External-Hex implants, PROVATA implants and Ø3.5 and Ø4.3 TRI-NEX implants is limited to replacement of maxillary and mandibular lateral and central incisors.

The ASC Solution Abutments and SI-BASE Abutments for Compact Conical Abutments are intended for use on straight Compact Conical Abutments with a straight mesostructure component.

SUBJECT DEVICE DESCRIPTION

This submission includes two major components which make up the ASC Solution and SI-BASE Abutments - The ASC Solution and SI-BASE Abutment Base and the mesostructure restoration. Two-piece and three-piece abutments models are included. Two-piece abutments consist of the ti-base abutment and mesostructure. Three-piece abutments consist of the ti-base abutment, mesostructure, and compatible compact conical abutments.

The ASC Solution and SI-BASE Abutments are standard premanufactured titanium alloy abutments for supporting a dental restoration and mesostructure. The dental laboratory is to fabricate the mesostructure restoration by CAD/CAM technique out of zirconia. The ASC Solution and SI-BASE Abutments then serve as the interface between the endosseous implant and the zirconia restoration. The 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, 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.

The ASC Solution and SI-BASE Abutments are compatible with the Southern Implants' Deep Conical, External Hex, Provata and Tri-Nex implants and screws. The abutments are manufactured from Titanium alloy conforming to ASTM F136 and are color coded by Titanium nitride coating (ASC Solution Abutments) or yellow anodizing (SI-BASE Abutments). The TiN coating and anodization processes are the same as used for previously cleared anodized titanium alloy devices in K163634. The Mesostructure restoration is to be manufactured from Zirconia - Sage Max NexxZr which has been previously cleared for use in K130991.

The digital workflow includes the following products (not subject devices to this submission):

- Ceramic material: Sage Max NexxZr Zirconia Restorative material (K130991)
- Cement: Ivoclar Vivadent Multilink Hybrid Abutment Cement (K130436)

- Intra-oral scanner: 3Shape E3 Desktop Scanner
- Abutment design software: 3Shape Abutment Designer Software (K151455)
- Milling machine: Roland DWX51D Milling Unit

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments; Biocompatibility testing per the FDA Guidance Document for Use of Standard ISO 10993-1, "Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process" and ISO 10993-5 "Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity"; validated sterilization instructions per ISO 17665-1 and ISO 17665-2; software validation testing per the FDA Guidance Document for Off-The-Shelf Software Use in Medical Devices; scanning and milling validation; and static and dynamic compression-bending according to ISO 14801. No clinical data was included in this submission.

Software verification and validation testing was provided for the subject abutment design library to demonstrate use with both the 3Shape Abutment Designer Software. The software verification and validation testing were conducted to demonstrate that the restrictions prevent design of the top half component of the multi-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" was performed on the previously cleared devices, K222457, PROVATA Implant System. The ASC Solution Abutments and SI-BASE Abutments were compared to the predicate devices. The ASC Solution and SI-BASE abutments 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:

K193084, TIB Abutment System, Southern Implants (Pty) Ltd.
K173706, Piccolo Implants and Accessories, Southern Implants (Pty) Ltd.
K222457, PROVATA Implant System, Southern Implants (Pty) Ltd.
K163634, External Hex Implants and Accessories, Southern Implants (Pty) Ltd.
K163060, Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd.
K053478, Endosseous Dental Implant System, Northern Implants (Pty) Ltd.
K070905, Endosseous Dental Implant System, Southern Implants (Pty) Ltd.
K130991, Zirconia restorative material, SageMaxx NexxZr
K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent
K151455, 3Shape Abutment Designer Software, 3Shape A/S

The primary predicate device is K193084.
The reference predicate devices are K053478, K070905, K173706, K163060, K163634, K22457 K130991, K130436, and K151455.

A comparison of the technological characteristics of the subject device and the predicate devices is provided in the following table:

Table of Substantial Equivalence – External Hex ASC Solution and SI-BASE Abutments

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	Angulated Screw Channel (ASC) Abutment System and SI-BASE Abutment System **Southern Implants (Pty) Ltd** **(External Hex ASC Abutments)**	**K193084** **TIB Abutment System** **Southern Implants (Pty) Ltd**	**K173706** **Piccolo Implants and Accessories** **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implants** **Southern Implants (Pty) Ltd**
Indications for Use Statement	The Angulated Screw Channel (ASC) Solution Abutments and SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The ASC Solution Abutments and SI-BASE Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a multi-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 intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.0 External-Hex implants are intended for use with a straight mesostructure component. The intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.4 and Ø4.0 External-Hex implants is limited to replacement of maxillary and mandibular lateral and central incisors.	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 consists 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 Piccolo Implants and Accessories are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing maxillary lateral incisors and mandibular incisors, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • immediate loading when good primary stability with appropriate occlusal loading is achieved, except in soft bone (type IV) where implant stability may be difficult to obtain.	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	NHA, PNP	NHA, PNP	DZE, NHA	DZE, NHA
Reason for Predicate/Reference	n/a	Abutment (general design and functioning) Software Compatibility Abutment Connection Type and Size	Ø3.0 External Hex Abutment Connection Type and Size Abutment Surface	External Hex Abutment Connection Type and Size Abutment Post Height
Abutment Types	External Hex Angulated Screw Channels External Hex SI-BASE Abutments	External Hex TiBase Abutments	Piccolo Abutments	Straight titanium abutments: Titanium cylinders Anatomic abutments

Prothesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration	Single-unit	Single-unit	Single-unit	Single-unit
Abutment Connection Interface	Southern Implants External Hex	Southern Implants External Hex	Southern Implants External Hex	Southern Implants External Hex
Abutment Connection Interface Diameters	Ø3.00 to Ø4.07	Ø3.43 to Ø4.07	Ø3.00	Ø3.43 to Ø4.07
Abutment Restorative Platform Diameter	Ø4.00 to Ø4.60	Ø4.30 to Ø5.10	Ø3.5	Ø3.40 to Ø4.05
Collar/Gingival Height	1.5mm	0.6, 1.5 or 3mm	0.6, 0.75 or 1 mm	1mm to 5mm
Abutment Post Height	Minimum 4.5mm	Minimum 4.5mm	Minimum 4mm	n/a
Abutment Angulation	0°	0°	0°	0°
Abutment Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136) or Titanium Grade 4 (ASTM F67) or Gold Alloy	Titanium Grade 5 Alloy (ASTM F136) or Titanium Grade 4 (ASTM F67) or Gold Alloy
Abutment Surface	Machined Knurled (grooved) Titanium nitride coated	Machined Knurled (grooved) Anodized	Machined Knurled (grooved) Titanium nitride coated	Machined Knurled (grooved) and smooth Titanium nitride coated
Restoration Material	Zirconia - Sage Maxx NexxZr (K130991)	Zirconia - Sage Maxx NexxZr (K130991)	n/a	n/a
Maximum Restoration Angle	20°	20°	20°	20°
Screw Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Screw Thread	M1.6, M2	1-72 unf-2b, M1.6, M1.8 and M2	M1.6	M2.0
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	n/a	n/a
CAD/CAM Manufacturing Workflow	WorkNC CAM software, Roland DWX51D milling unit	WorkNC CAM software, Roland DWX51D milling unit	n/a	n/a
How Provided				
Sterility	Non-sterile	Non-sterile	Sterile: Titanium Abutments Non-sterile: Gold Abutments, Passive Abutments	Sterile: Titanium Abutments
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

Table of Substantial Equivalence – Internal Connection ASC Solution and SI-BASE Abutments

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	Angulated Screw Channel (ASC) Abutment System and SI-BASE Abutment System **Southern Implants (Pty) Ltd (Internal Connection ASC Abutments)**	**K193084** **TIB Abutment System** **Southern Implants (Pty) Ltd**	**K222457** **PROVATA Implant System** **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implants** **Southern Implants (Pty) Ltd**
Indications for Use Statement	The Angulated Screw Channel (ASC) Solution Abutments and SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The ASC Solution Abutments and SI-BASE Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a multi-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 intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the Ø3.3 PROVATA implants and Ø3.5/Ø4.0 Deep Conical implants are intended for use with a straight mesostructure component. The intended use for the engaging ASC Solution Abutments and SI-BASE Abutments used with the PROVATA implants and Ø3.5 and Ø4.3 TRI-NEX implants is limited to replacement of maxillary and mandibular lateral and central incisors.	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 consists 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 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. 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.	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	NHA, PNP	NHA, PNP	NHA, PNP	DZE, NHA
Reason for Predicate/Reference	n/a	Abutment (general design and functioning) Software Compatibility Abutment Connection Type and Size	Internal Hex Abutment Connection Type and Size	Abutment material Surface treatment Packaging methods

Abutment Types	All Southern Implants Internal Hex Angulated Screw Channel Abutments All Southern Implants Internal Hex SI-BASE Abutments	All Southern Implants Internal Hex TiBase Abutments	Narrow PROVATA TiBase Abutment	Compact Conical Abutments
Prothesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Screw-retained
Restoration	Single-unit	Single-unit	Single-unit	Multi-unit
Abutment Connection Interface	Southern Implants Internal Hex Connections	Southern Implants Internal Hex Connections	Southern Implants Internal Hex Connections	Southern Implants External Hex
Abutment Connection Interface Diameters	Ø3.30 to Ø4.07	Ø3.50 to Ø4.30	Ø3.30	Ø3.0, 3.43, 4.05, 5.0 and 6.0mm
Abutment Restorative Platform Diameter	Ø4.00 to Ø4.60	Ø4.30 to Ø5.00	Ø3.85	Ø4.8 and Ø6.0
Collar/Gingival Height	1.5mm	0.6 to 3mm	1.5mm or 3mm	1.58, 2, 3, 4, and 5.5mm
Abutment Post Height	Minimum 4.5mm	Minimum 4.5mm	Minimum 4.5mm	n/a
Abutment Angulation	0°	0°	0°	0° - 30°
Abutment Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Abutment Surface	Machined Knurled (grooved) Titanium nitride coated Anodized	Machined Knurled (grooved) Anodized	Machined Knurled (grooved) Anodized	Machined Titanium nitride coated
Restoration Material	Zirconia - Sage Maxx NexxZr (K130991)	Zirconia - Sage Maxx NexxZr (K130991)	Zirconia - Sage Maxx NexxZr (K130991)	n/a
Maximum Restoration Angle	20°	20°	20°	n/a
Screw Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Screw Thread	1-72 unf-2b, M1.6, M1.8, M2	1-72 unf-2b, M1.6, M1.8 and M2	M1.6	M1.4
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	3Shape E3 Desktop Scanner (3Shape A/S) 3Shape Abutment Designer Software	n/a
CAD/CAM Manufacturing Workflow	WorkNC CAM software, Roland DWX51D milling unit	WorkNC CAM software, Roland DWX51D milling unit	WorkNC CAM software, Roland DWX51D milling unit	n/a
How Provided				
Sterility	Non-sterile	Non-sterile	Non-sterile	Sterile
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

Table of Substantial Equivalence – Compact Conical ASC Solution Abutments and SI-BASE Abutments

Comparison	Subject Device	Reference Device	Primary Predicate Device	Reference Device
	Angulated Screw Channel (ASC) Abutment System and SI-BASE Abutment System **Southern Implants (Pty) Ltd (Internal Connection ASC Abutments)**	**K053478/K070905** **Endosseous Implant and Accessories** **Northern Implants (Pty) Ltd/ Southern Implants (Pty) Ltd**	**K193084** **TIB Abutment System** **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implants** **Southern Implants (Pty) Ltd**
Indications for Use Statement	The Angulated Screw Channel (ASC) Solution Abutments and SI-BASE Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The ASC Solution Abutments and SI-BASE Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a multi-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 ASC Solution Abutments and SI-BASE Abutments for Compact Conical Abutments are intended for use on straight Compact Conical Abutments with a straight mesostructure component.	The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous protheses, or full arch protheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.	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 consists 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.	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	NHA, PNP	DZE	NHA, PNP	DZE, NHA
Reason for Predicate/Reference	n/a	Abutment (general design and functioning) Abutment Connection Type and Size Abutment material	Software Compatibility Sterility	Abutment material Surface treatment Packaging methods
Abutment Type	Angulated Screw Channel Compact Conical Abutments SI-BASE Compact Conical Abutments	Titanium Cylinders for Compact Conical Abutments Compact Conical Abutments	All non-engaging TIB Abutments	Compact Conical Abutments
Prothesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Screw-retained

Restoration	Multi-unit	Multi-unit	Single-unit	Multi-unit
Abutment Connection Interface	Ø4.8 Compact Conical Ø6.0 Compact Conical	Ø4.8 Compact Conical Ø6.0 Compact Conical	All Southern Implants Connection Types	External Hex (Ø3.0, 3.43, 4.05, 5.0 and 6.0mm)
Abutment Restorative Platform Diameter	Ø5.20 and Ø6.40	Ø5.20 and Ø6.40	Varying	Ø4.8 and Ø6.0
Collar/Gingival Height	1mm	1mm	0.6, 1.5 or 3mm	1.58, 2, 3, 4, and 5.5mm
Abutment Post Height	Minimum 4.5mm	n/a	Minimum 4.5mm	n/a
Abutment Angulation	0°	0°	0°	0°
Abutment Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 3 (ASTM F67)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Abutment Surface	Machined Knurled (grooved) Titanium nitride coated Anodized	Machined Knurled (grooved)	Machined Knurled (grooved) Anodized	Machined Knurled (grooved) Titanium nitride coated
Restoration Material	Zirconia - Sage Maxx NexxZr (K130991)	n/a	Zirconia - Sage Maxx NexxZr (K130991)	n/a
Maximum Restoration Angle	0°	20°	20°	n/a
Screw Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)	Titanium Grade 5 Alloy (ASTM F136)
Screw Thread	M1.4	M1.4	Varying	M1.4
CAD/CAM Design Workflow	3Shape E3 Desktop Scanner (3Shape A/S) 3Shape Abutment Designer Software	n/a	3Shape E3 Desktop Scanner (3Shape A/S) 3Shape Abutment Designer Software	n/a
CAD/CAM Manufacturing Workflow	WorkNC CAM software, Roland DWX51D milling unit	n/a	WorkNC CAM software, Roland DWX51D milling unit	n/a
How Provided				
Sterility	Non-Sterile	Sterile	Non-sterile	Sterile
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

The Indications for Use Statement for the subject devices is very similar to the predicate device and reference devices, differing in device name and the addition of paragraphs stating the intended use of the various subject devices. The subject and predicate device Indications for Use statements have identical wording regarding the system integration of the devices into digital dentistry workflows. The Indications for Use Statements of the reference predicates K173706 and K222457, cover the additional paragraphs specified in the subject device's Indication for Use Statement. K222457 covers the indications limited to replacement of maxillary and mandibular lateral and central incisors, whereas K173706 covers indications for use with a straight mesostructure component.

The subject device's Indications for Use Statement combines the relevant features of both predicate and reference Indications for Use statements. These minor differences do not raise new concerns of safety, effectiveness or substantial equivalence as the combined Indications for Use Statements express shared intended use.

The primary predicate device K193084 is for substantial equivalence of the subject device abutment designs and abutment connection types. The subject device abutments have the similar designs, identical connection types and are both two-piece abutments with a premanufactured titanium base making up the first piece, and a ceramic composite intended to be bonded to the titanium base making up the second piece of the abutment. Design differences are covered by specified reference predicate devices. The abutment design is thus substantially equivalent to that of the primary predicate and reference predicates.

The primary predicate and the subject devices have the identical maximum angulation for the ceramic restoration and follow an equivalent design workflow. In the design workflow the primary predicate and subject devices use the same scanners and software to design the restoration.

The subject device is also substantially equivalent to the primary predicate with reference to the abutment's restoration material with the subject and the primary predicate both making use of a ceramic composite both performing appropriate performance testing on the ceramic component of the two-piece abutment. The titanium abutment materials for both the subject devices and primary predicate is a Titanium Alloy (ASTM F136), the screw material is Titanium for both the subject and primary predicate. Both the subject and the primary predicate devices are provided non-sterile. Thus, the abutment materials and method provided of the subject device are substantially equivalent to that of the primary predicate.

Substantial equivalence of the subject device and primary predicate 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 device in K193084.

The reference device (K163634) is for substantial equivalence of abutment material, surface treatment and packaging methods. The subject device abutments are manufactured from Titanium alloy conforming to ASTM F136 and are color coded by anodizing and titanium nitride coating. The anodization and coating processes are the same as that used for the reference device (K163634). Both the subject and the reference device are packaged with the same methods for single use. Thus, the material, surface treatment and packaging methods of the subject device is considered substantially equivalent to that of the reference device.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* was performed. Dynamic testing was performed on worst-case subject device constructs. The results from the worst-case construct bench testing demonstrated fatigue performance of the subject device that exceeds its indication and is supported by bench testing previously cleared in K173706 and K222457.

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 K193084. Furthermore, biocompatibility testing per the FDA Guidance Document for Use of Standard ISO 10993-1, "Biological evaluation of medical devices – Part1: Evaluation

and testing within a risk management process" was performed.

The inclusion of the 3Shape software (K151455) was validated with performance testing per the FDA Guidance Document for Off-The-Shelf Software Use in Medical Devices.

Overall, the subject device has the following similarities to the predicate devices:
• A similar intended use
• Incorporates the same basic design
• Incorporates the same or very similar materials,
• Follows the equivalent design and manufacturing workflows,
• Incorporates the same abutment surface treatment and packaging,
• Has similar fatigue limits

CONCLUSION

The subject device and the predicate devices all incorporate the same materials, basic design and intended use. The subject device and the predicate devices are for substantial equivalence of surface treatment and patient usage, and are provided non-sterile. The subject device and the primary predicate follow the same design and manufacturing CAD/CAM workflows.

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