April 17, 2023

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

Re: K222469
Trade/Device Name: TIB Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: March 14, 2023
Received: March 14, 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)*
K222469

Device Name
TIB Abutments

Indications for Use *(Describe)*
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 intended use for the TiB narrow abutments used with the Ø3.0 mm External hex and Ø3.0 mm Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular lateral and central incisors.

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

TIB Abutment System

Southern Implants (Pty) Ltd

April 17, 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	TIB Abutment System
Common name	Dental Abutment
Classification name	Endosseous Dental Implant Abutment
Classification regulation	21 CFR 872.3630, Class II
Product Code	NHA, PNP
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate device for the subject device Narrow TIB Abutments is K193084. The reference devices are K163060, K173706 and K220841.

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 intended use for the TiB narrow abutments used with the Ø3.0 mm External hex and Ø3.0 mm Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular lateral and central incisors.

SUBJECT DEVICE DESCRIPTION

The Narrow TIB Abutment bases 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 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 DC Ø3.0mm Narrow TiB abutments are only to be placed straight in the patient. Occlusal loading forces are only to be applied through the central longitudinal axis of the implant body.

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 subject Narrow TIB Abutments are compatible with the Southern Implants' Deep Conical and External Hex implants and screws. The subject TIB abutment bases are manufactured from Titanium alloy conforming to ASTM F136 and are color coded by gold anodizing. The anodization process is the same as used for previously cleared anodized titanium alloy devices in K193084. The mesostructured 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
- Lab scanner: 3Shape E3 Desktop Scanner (3Shape A/S)
- Abutment design software: 3Shape Abutment Designer Software (K151455)
- Milling machine: Roland DXW51D

PERFORMANCE DATA

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

biocompatibility (referenced from K193084); static and dynamic compression-bending according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*, validated sterilization instructions per ISO 17665-1 and ISO 17665-2; 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", 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 was included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Southern Implants (Pty) Ltd submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K193084, TIB Abutment System, Southern Implants (Pty) Ltd.
K163060, Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd.
K173706, Piccolo Implants and Accessories, Southern Implants (Pty) Ltd.
K220841, PrimeTaper EV Dental Implants Ø3.0, DS Implants abutments with EV connection (XS)

The primary predicate device for the subject device Narrow TIB Abutment is K193084. The reference devices are K163060, K173706 and K220841.

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

Table of Substantial Equivalence – External Hex Narrow TIB Abutments

Comparison	**Subject Device**	**Primary Predicate Device**
	TIB Abutment System **Southern Implants (Pty) Ltd** **(External Hex Narrow TIB Abutment)**	**K193084** **TIB Abutment System** **Southern Implants (Pty) Ltd**
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 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 intended use for the TiB narrow abutments used with the Ø3.0 mm External hex and Ø3.0 mm Deep Conical implants is limited to replacement of maxillary lateral incisors 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.
Product Code	NHA, PNP	NHA, PNP
Item Code	TIBS-EX-30-C1.5 TIBS-EX-30-C3	TIB-EX-34 TIB-EX-34-C1.5

		TIB-EX-34-C3 Variations available for all External Hex connection sizes.
Reason for Predicate/Reference	n/a	Abutment (general design and functioning) Software Compatibility
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 3mm	0.6, 1.5 or 3mm
Maximum Abutment Top-Cap Angulation	20°	20°
Implant Connection	External Hex	External Hex
Post Height	Minimum 4.5mm	Minimum 4.5mm
Abutment Restorative Platform Diameter	3.85mm	4.3 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
Sterility	Provided non-sterile	Provided non-sterile
Usage	Single-patient, single-use	Single-patient, single-use

Table of Substantial Equivalence – Deep Conical Narrow TIB Abutments

Comparison	Subject Device	Primary Predicate Device
	TIB Abutment System **Southern Implants (Pty) Ltd** **(Deep Conical Narrow TIB Abutment)**	**K193084** **TIB Abutment System** **Southern Implants (Pty) Ltd**
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 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 intended use for the TiB narrow abutments used with the Ø3.0 mm External hex and Ø3.0 mm Deep Conical implants is limited to replacement of maxillary lateral incisors 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.
Product Code	NHA, PNP	NHA, PNP
Item Code	TIBS-DC3-C1.5 TIBS-DC3-C3 TIBS-DC4-C1.5 TIBS-DC4-C3	TIB-DC4 TIB-DC4-CSET Variations available for all Deep Conical connection sizes.
Reason for Predicate/Reference	n/a	Abutment (general design and functioning) Software Compatibility
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 3mm	0.6, 1.5 or 3mm
Maximum Abutment Top-Cap Angulation	0° (for Ø3mm implant) and 20°	20°
Implant Connection	Deep Conical	Deep Conical
Post Height	Minimum 4.5mm	Minimum 4.5mm
Abutment Restorative Platform Diameter	3.85mm	4.5 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
Sterility	Provided non-sterile	Provided non-sterile
Usage	Single-patient, single-use	Single-patient, single-use

Subject device Narrow TIB Abutments

The primary predicate device K193084 is for substantial equivalence of the subject device Narrow TIB abutment designs. The subject device abutments have similar indication for use, equivalent design, 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. The primary predicate and subject device have comparable designs differing only in dimension. All the predicate device design features for example restorative platform, anodizing, post and grooves are present. The Indications for Use Statement for the subject device is similar to the reference device K193084 only with restrictions imposed on the Ø3.0 Deep Conical and Ø3.0 External Hex abutments. The abutment design and indications for use are thus substantially equivalent to that of the primary predicate.

The primary predicate and the subject device have the identical maximum angulation for the ceramic restoration and follow an equivalent design workflow. With the only exception being the Ø3.0 Deep Conical Narrow TiB abutments which are not intended for angled placement. The DC Ø3.0mm Narrow TiB abutments are only to be placed straight in the patient. Occlusal loading forces are only to be applied through the central longitudinal axis of the implant body. 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 abutments restoration material with the subject and the primary predicate both making use of a ceramic composite material (K130991). The titanium abutment material for both the subject device 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 devices K173706 and K163060 are for substantial equivalence of the abutment connection types namely External Hex and Deep Conical. The reference devices contain the identical connection types and sizes to those of the subject devices.

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 reference devices K193084 and K220841 are included as reference devices for substantial equivalence in terms of fatigue strength of the worst-case combinations.

CONCLUSION

The subject devices and the primary predicates have similar indications for use, operating principles, have similar technological characteristics and are made of the same materials. The subject devices and the predicate devices encompass similar physical designs. The subject devices and the primary predicate devices are packaged identically and are all 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