October 27, 2020

Southern Implants (Pty) Ltd
Lauranda Breytenbach
Head of Regulatory Affairs and Quality
1 Albert Road
Irene, Gauteng 0062
REPUBLIC OF SOUTH AFRICA

Re: K193084
Trade/Device Name: TIB Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: October 19, 2020
Received: October 20, 2020

Dear Lauranda Breytenbach:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193084

Device Name
TIB Abutment System

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.

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

K193084

TIB Abutment System

Southern Implants (Pty) Ltd

October 27, 2020

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	Lauranda G. Breytenbach Head of Regulatory Affairs and Quality Email: lauranda.b@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 is K180899
The reference predicate devices are K181359, K111421, K163634, K130991, K130436 and K151455

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.

SUBJECT DEVICE DESCRIPTION

This submission includes two major components which make up the TIB Abutment - The TIB Abutment Base and the mesostructure restoration.

The TIB Abutment base is a standard premanufactured titanium alloy abutment 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 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 TIB Abutments are compatible with the Southern Implants' Deep Conical, External Hex, Provata and Tri-Nex implants and screws. The 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 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)
- Desktop scanner: 3Shape E3 Desktop Scanner (The scanner is 510(k) exempt under regulation 872.3661)
- Abutment design software: 3Shape Abutment Designer Software (K151455)
- Milling machine: Roland DWX51D Milling Machine

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.

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:

K180899, Universal Base Abutment, Nobel Biocare
K111421, Sirona Dental CAD/CAM System, Dentsply Sirona
K181359, InterActive SMARTBase Abutments, Implant Direct
K163634, External Hex Implants, Southern Implants
K130991, Zirconia restorative material, SageMaxx NexxZr
K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent
K151455, 3Shape Abutment Designer Software, 3Shape A/S

The primary predicate is K180899.
The reference predicate devices are K181359, K111421, K163634, K130991, K130436 and K151455.

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

Characteristics	**Subject Abutment**	**Primary Predicate**	**Reference Predicates**		
	Southern Implants TIB Abutment	**Universal Base Abutment (K180899)**	**InterActive SMARTBase Abutments (K181359)**	**Sirona Dental CAD/CAM System (K111421)**	**Southern Implants External Hex (K163634)**
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 – Enamic (K153645) bonded to Universal Base Abutment mounted onto the implant and fixed with a screw	Abutment body consisting of a titanium base and supplied with a fixation screw. The bases are provided with straight, angled, and modified zirconia tops for patient specific devices. The devices are also provided without a zirconia top and a superstructure or hybrid crown or bridge can be milled to fit the bases intended to be manufactured at Implant Direct Manufacturing facility's	The TiBase is a premanufactured prosthetic component directly connected to endosseous dental implants with a screw and is intended for use as an aid in prosthetic rehabilitation.	Sterile: Cover Screw , Healing Caps, Healing Abutments, Titanium Abutments, Anatomic Abutments, Cosmetic Abutments, Compact Conical Abutments Non-sterile: Gold Abutments, Chrome Cobalt Abutments, Passive Abutments
Maximum Abutment Angulation	20°	20°	30°	20°	-
Restoration Material	Zirconia - Sage Maxx NexxZr (K130991)	Enamic (K153645)	Zenostar MT	Cercon HT	-
Post Height	Minimum 4.5mm	Minimum 5.2mm	Single Unit - Minimum 4 mm Multi-Unit - Minimum 4 mm	Minimum 4mm	-

Characteristics	Subject Abutment	Primary Predicate	Reference Predicates		
	Southern Implants TIB Abutment	**Universal Base Abutment (K180899)**	**InterActive SMARTBase Abutments (K181359)**	**Sirona Dental CAD/CAM System (K111421)**	**Southern Implants External Hex (K163634)**
Screw Thread	1-72 unf-2b, M1.6, M1.8 and M2	Not available	M1.6, M2	M1.6, M2 (NobelActive)	M2
Compatible Implant Platforms	Southern Implants: External Hex Implants Provata Implants Deep Conical Implants Tri-Nex Implants	Nobel Biocare External Hex Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	InterActive SMARTBase abutments are compatible at the implant level with InterActive (3.0mm and 3.4mm Platform) and SwishActive (3.0mm and 3.4mm Platform) system implants.	The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), Straumann Synocta (K061176), Straumann Bone Level (K053088), Biomet 3i Certain (K014235), Nobel Biocare Active (K071370).	Southern Implants External Hex Implants
CAD/CAM Design Workflow	3Shape E3 Desktop Scanner (3Shape A/S). 3Shape Abutment Designer Software (Shape A/S)- K151455	3Shape Intra oral scanner Trios (3Shape A/S). 3Shape Abutment Designer Software (Shape A/S)- K151455	3M Tru-Definition, ITero Scanner 3Shape Abutment Designer Software (3Shape A/S) - K151455	Sirona software – inlab 15.0 and above Sirona software – CEREC 4.4 and above	-
CAD/CAM Manufacturing Workflow	WorkNC CAM software, Roland DWX51D milling unit	CORiTEC milling unit (imes-icore)	Wieland-Zenotec Select & Zenotec CAM	CEREC MCXL product family	-
Mechanical Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801
Titanium Abutment Material	Titanium Grade 5 Alloy (ASTM F136)	Titanium Vanadium Alloy (ASTM F136)	Titanium	TiBase - Titanium 6AL4V	Titanium Grade 5 Alloy (ASTM F136)
Abutment Surface Treatment	Machined and Anodized gold		Abutments are titanium anodized gold and pink (grooves are machined for cement adhesion).	Cemented surfaces are blasted with aluminum oxide.	Anodized, Grooved
Screw Material	Titanium Grade 5 (ASTM F136)	Titanium	Titanium	Titanium	Titanium Grade 5 (ASTM F136)
Sterility	Supplied non-sterile	Supplied non-sterile	Supplied non-sterile	Supplied non-sterile	Supplied sterile
Use	Single-Use		Single-Use	Single-Use	Single-Use
Indications for Use	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	The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of	InterActive/SwishActive Implant System consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple unit restorations and terminal or intermediate	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and	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.

Characteristics	Subject Abutment	Primary Predicate	Reference Predicates		
	Southern Implants TIB Abutment	**Universal Base Abutment (K180899)**	**InterActive SMARTBase Abutments (K181359)**	**Sirona Dental CAD/CAM System (K111421)**	**Southern Implants External Hex (K163634)**
	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.	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 Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	SMARTBase abutment support for fixed bridgework. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The SMARTBase Abutments consist of two major parts. Specifically, the titanium base and zirconia top components make up a two-piece abutment. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Narrow Diameter (3.2, 3.3mm) Implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.	CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure.	Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

The Indications for Use Statement for the subject device is the same as that of the primary predicate device K180899, except for the names of the devices and the type of scanner.

The primary predicate device K180899 is for substantial equivalence of the subject device abutment design. The subject device abutments have the equivalent design 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. The abutment design is 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. In the design workflow the primary predicate uses a different scanner but the same software to design the restoration. The design workflow differing with the scanner does not impact demonstrating substantial equivalence. The difference in scanner was shown to not affect substantial equivalence by way of software validation, scanning and milling validation, and static and dynamic compression-bending according to ISO 14801.

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 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. The different manufacturing and ceramic material comparison were addressed with 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 validated sterilization instructions per the FDA Guidance Document for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling.

The reference predicate K181359 is for substantial equivalence of the Subject Device screw thread, manufacturing workflow, abutment surface treatment and usage. The subject device makes use of the same screw threads as the reference device (K181359) with a difference of the addition of the 1-72 unf-2b (1.85mm) and M1.8 screw threads. The screw threads differing with the addition of intermediary screw threads does not impact demonstrating substantial equivalence, and this was shown with static and dynamic compression-bending according to ISO 14801.

In terms of the manufacturing workflow, the subject device makes use of the WorkNC CAM software and a Roland DWX51D milling unit. The reference device (K181359) Makes use of Zenotec CAM and Wieland-Zenotec Select milling unit. While both are different brands, both devices make use of CAM software, communicating with a milling unit. The manufacturing workflow differing with CAM software and milling unit brands does not impact demonstrating substantial equivalence, and this was shown by of software validation, scanning and milling validation, and static and dynamic compression-bending according to ISO 14801.

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. The anodization process is 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.

The reference predicate K111421 is for substantial equivalence of the compatible implant platforms. The subject device is designed to connect directly to the Southern Implants External Hex, Internal Hex, Deep Conical and Tri-Nex connection types. While the reference device (K111421) is designed to connect directly to multiple different implant systems, which together encompass the same range of implant platform types as that of the subject device. This, with the addition of Mechanical ISO 14801 Fatigue Testing of all four implant platforms proves substantial equivalence of the compatible implant platforms.

The post height of the subject device is indicated to a minimum of 4.5mm. The primary predicate (K180899) is indicated to a minimum of 5.2mm, while the reference device (K181359) is indicated to a minimum of 4mm. The subject device post height lies between these two predicate minimums and is thus substantially equivalent.

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 K163634. 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:
• Has the same 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 a similar fatigue limit

CONCLUSION

The subject device and the primary predicate have the same intended use, except for the different scanner. The subject device and predicate devices all incorporate the same materials and basic design. 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.