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

June 8, 2018

Re: K173706
Trade/Device Name: Piccolo Implants and Accessories
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 19, 2018
Received: March 23, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173706

Device Name
Piccolo Implants and Accessories

Indications for Use *(Describe)*
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.

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.

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510(k) Summary

Piccolo Implants and Accessories

Southern Implants (Pty)

Ltd. June 8, 2018

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 Breytenbach Regulatory Affairs and Quality

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Piccolo Implants and Accessories
Common Name	Dental implant Dental implant abutment
Classification Name	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations Product Code	21 CFR 872.3640, Class II DZE (Primary product code) NHA (Secondary product code)
Classification Panel Reviewing Branch	Dental Products Panel Dental Devices Branch

PREDICATE DEVICE INFORMATION

	Manufacturer	**Device Name**	**K number**
Primary:	Southern Implants (Pty) Ltd.	Deep Conical (DC) Implants and Accessories	K163060
Reference:	Southern Implants (Pty) Ltd.	External Hex Implants and Accessories	K163634
Reference:	Astra Tech AB	OsseoSpeed™ Plus	K120414

INDICATIONS FOR USE

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.

SUBJECT DEVICE DESCRIPTION

The Piccolo Implants and Accessories is a threaded root-form dental implant and abutment system.

The implants are Ø3.0 mm in diameter with lengths of 8.5, 10, 11.5, 13 and 15 mm. There is a standard version and a MSC version with a 1 and 3 mm machined surface coronal region respectively. The rest of the body has a roughened surface. The system has an external hexagonal implant-abutment interface.

The following abutments are included in the range: Cover Screws, Healing Abutments, Titanium Abutments (all made from commercially pure titanium (CPTi)), Gold Abutments (made from gold alloy), Passive Abutments and Compact Conical Abutments (both made from titanium alloy). All abutments (except the one-piece abutments) are used with a titanium alloy retaining screw. An overview is given in Table 1.

Table 1: List of Abutments Included in the Subject Device

Abutment Model	Type	Body/gingival height	Platform Ø	Body Ø
Cover Screws	One-piece	1.2	Ø3.0	Ø3.0
Healing Abutments	One-piece Narrow	3, 4, 6	Ø3.0	Ø3.0
	One-piece Wide	3, 4, 6	Ø3.0	Ø4.0
Titanium Abutments	Engaging	1	Ø3.0	Ø3.5
	Non-engaging	1		
Gold Abutments	Engaging	0.75	Ø3.0	Ø3.5
	Non-engaging	0.75		
Passive Abutments	Engaging	0.6	Ø3.0	Ø3.5
	Non-engaging	0.6		
	Engaging (Vertical)	1.0		Ø3.0
Compact Conical Abutments	One-piece	1.7, 3, 4, 5.5	Ø3.0	Ø4.8

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include:engineering analysis, dimensional analysis, and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. No clinical data were included in this submission.

The sterilization method for the subject device is the same as the primary predicate (K163060) and reference device (K163634). The sterilization method is Gamma radiation and has been validated in accordance with ISO 11137-1 *Sterilization of health care products - radiation - part 2: Requirements for development, validation, and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products - radiation - part 1: establishing the sterilization dose*. The sterilization method is moist heat for the devices to be end user sterilized and has been validated in accordance with ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*. The Limulus Amebocyte Lysate (LAL) test for detection and quantitation of bacterial endotoxin was conducted in accordance with USP 39-NF 34 <85> *Bacterial Endotoxin Test, using the kinetic chromogenic test method.*

The packaging for the subject device is the same as the primary predicate (K163060) and reference device (K163634). Packaging was validated in accordance with ISO 11607 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.* Accelerated aging per ASTM-F-1980 *Standard guide for accelerated aging of sterile medical device packages* has been applied on the final packaging followed by validating durability to peel and dye tests conditions, in order to substantiate 5 years shelf life.

The subject device is manufactured from the same material using the same manufacturing method as the applicant's own primary predicate (K163060) and reference device (K163634), has the same intended use, and the same patient contact type and duration.

The subject device is biocompatible in accordance with ISO 10993-1. Cytotoxicity testing in accordance with ISO 10993-5 was also performed.

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:

K163060, Southern Implants (Pty) Ltd., Deep Conical (DC) Implants and Accessories

K163634, Southern Implants (Pty) Ltd., External Hex Implants and Accessories

K120414, Astra Tech AB, OsseoSpeed™ Plus

A table comparing the subject device and primary predicate devices is provided in Table 2.

Table 2: Predicate 1 and Subject Device Comparison Table

	Subject Device	**Primary Predicate**
Submission name	**Piccolo Implant and Accessories**	**Deep Conical (DC) Implants and Accessories**
Manufacturer	**Southern Implants (Pty) Ltd.**	**Southern Implants (Pty) Ltd.**
510(k) Number		**K163060**
Indications for Use Statement	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 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	DZE, NHA	DZE, NHA
Intended Use	Dental implant system for the functional and esthetic replacement of missing teeth.	Dental implant system for the functional and esthetic replacement of missing teeth.
Implant Body Design	Threaded root-form implants: Tapered	Threaded root-form implants: Tapered Cylindrical Co-axis tapered Co-axis cylindrical
Implant body diameters and lengths (mm)	Ø3.0: length 8.5, 10, 11.5, 13, 15	Ø3.0: length 9, 11, 13, 15 Ø3.5 – Ø5.0: length 6 – 15
Implant Material	CPTi – (cold worked)	CPTi – (cold worked)
Implant Surface	Southern Implants' roughened surface Machined collar versions available	Southern Implants' roughened surface
Implant Sterilization	Sterile – irradiation	Sterile – irradiation
Implant / Abutment Interface	External Hex	Deep Conical
Abutment Designs	Cover screw Healing abutment	Cover Screw Healing Abutment, Healing Caps

	Subject Device	Primary Predicate
	Titanium Abutment Gold Abutment Passive Abutments Compact Conical Abutment	Titanium Abutment, Angled Abutments Overdenture Abutment Gold Abutment Passive Abutments Compact Conical Abutment
Abutment platform diameters	Ø3.0	Ø3.0, Ø3.5, Ø4.0, Ø5.0
Abutment angle	0° only	0°, 12°, 24°
Abutment Material	CPTi Titanium alloy Gold alloy	CPTi Titanium alloy Gold alloy
Abutment Surface	Machined Knurled (grooved) Titanium nitride coated	Machined Knurled (grooved) Titanium nitride coated
Restoration	Single-unit or multi-unit	Single-unit or multi-unit

Primary predicate (K163060) is for substantial equivalence of the diameter, materials and surface of the implants and abutments. The subject device implants have the same outer diameter as the primary predicate Ø3.0 implants. The subject device is made from the same material, in the same manufacturing facilities, with the same surface treatment as implants in primary predicate (K163060). The subject device has Ø3.0 abutments of the same type as the primary predicate (K163060) with substantially equivalent design and materials. Primary predicate (K163060) has implants with a range of sizes including diameter 3.0 mm implants. The subject device only has diameter 3.0 mm implants. The differences in wording of the indications for use statement reflect this difference, but with regards to the Ø3.0 implant and accessories the indications for use statements are substantially equivalent.

Reference device (K163634) is for substantial equivalence of the design features of the subject device implants and abutments. The subject device Piccolo implants are Ø3.0 tapered implants with a similar shape, lengths, thread, flutes, taper, apex, collar and connection interface to the corresponding Ø3.25 tapered implant in reference device (K163634).

The subject device and all primary predicate (K163060) and reference devices (K163634, K120414) are provided sterile for single-patient, single-use.

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are identical in formulation, processing, component interactions, and storage conditions to the devices in primary predicate (K163060) and reference device (K163634).

CONCLUSION

The subject device and the primary predicate (K163060) and reference devices (K163634, K120414) have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device and the primary predicate (K163060) and reference devices (K163634, K120414) are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence of the subject device to the primary predicate and reference devices listed above.