May 7, 2020

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

Re: K192651
Trade/Device Name: ZAGA Zygomatic System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 23, 2020
Received: April 7, 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)*
K192651

Device Name
ZAGA Zygomatic System

Indications for Use *(Describe)*
Southern Implants ZAGA Zygomatic System implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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

ZAGA Zygomatic System

K192651

May 6, 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	ZAGA Zygomatic System
Common Name	Dental implant
Classification Name	Endosseous dental implant
Classification Regulation	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

The primary predicate device is K173343.
The reference devices are K163634 and K181703.

INDICATIONS FOR USE STATEMENT

Southern Implants ZAGA Zygomatic System implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

This submission includes partially threaded root-form dental implants and mating abutments designed for placement into the zygomatic bone. All implants are provided with an external hexagon abutment interface angled 55° at the head of the implant. The implants are provided in two designs: the ZAGA Regular zygomatic implant, coronally and apically threaded, diameter 4.3 mm (coronal) tapering to 3.4 mm (apical), in overall lengths ranging of 35 mm and 55 mm; and the ZAGA Advanced zygomatic implant, apically threaded, diameter 4.3 mm (coronal) tapering to 3.4 mm (apical), in overall lengths ranging from 30 mm to 52.5 mm, with a flat cut into the buccal-facing side of the implant body.

This submission includes designs of the ZAGA screw-retained abutments in four gingival heights (1.5, 2.5, 3.5, and 4.5 mm) for use with the ZAGA zygomatic implants. The subject device abutments are for support of screw-retained overdenture prosthetic restorations.

All subject device implants are manufactured from unalloyed titanium conforming to ASTM F67. The apically threaded portions of the implants have the identical aluminum oxide grit-blasted surface as the implants cleared in K173343. The subject device ZAGA screw-retained abutments are manufactured from unalloyed titanium conforming to ASTM F67, and have the same anodized surface treatment as the healing abutments cleared in K163634. All of the subject device components are manufactured in the same facilities using the same manufacturing processes as used for the Southern Implants predicate devices previously cleared in K173343 and K163634.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K173343 and K163634); engineering analysis; dimensional analysis; sterilization validation according to ISO 11137-1, ISO 11137-2; bacterial endotoxin according to USP 39-NF34<85>; sterile barrier shelf life (referenced from K173343); and static an dynamic compression-bending according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. No clinical data were 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:

K173343, Zygomatic Implant System, Southern Implants (Pty) Ltd.
K163634, External Hex Implants, Southern Implants (Pty) Ltd.
K181703, Straumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments, Straumann USA, LLC (on behalf of Institut Straumann AG)

The primary predicate device is K173343.
The reference devices are K163634 and K181703.

A comparison of the technological characteristics of the subject device and the primary predicate device K173343 is provided in the following table.

Comparison	Subject Device **ZAGA Zygomatic System** **Southern Implants (Pty) Ltd**	Primary Predicate Device **K173343** **Zygomatic Implant System** **Southern Implants (Pty) Ltd**
Indications for Use Statement	Southern Implants ZAGA Zygomatic System implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Southern Implants Zygomatic System Standard implants, Zygan (narrow apex) implants, and Oncology implants are intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Implant		
Implant Design	Partially threaded root-form implants for placement into the zygoma.	Zygan and Oncology: Partially threaded root-form implants for placement into the zygoma.
Implant Diameter	ZAGA Regular: 4.3 mm (coronal) taper to 3.4 mm (apical) ZAGA Advanced: 4.3 mm (coronal with 3.35 mm flat) taper to 3.4 mm (apical)	Zygan: 4.3 mm (coronal) taper to 3.4 mm (apical) Oncology: 4.3 mm (coronal) taper to 3.8 mm (apical)
Implant Length	ZAGA Regular: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm ZAGA Advanced: 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5 mm	Zygan: 30, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5 mm Oncology: 27.5, 30, 32.5, 37.5, 42.5, 47.5 mm
Threaded Lengths	ZAGA Regular: 5 mm coronal + 17 mm apical ZAGA Advanced: 17 mm (apical only)	Standard implant: Fully threaded Zygan implant: 6 mm coronal + 15 mm apical Oncology implant: 20 mm (apical only)
Platform Angle, Relative to orthogonal to implant long axis	55° angulation at head of implant	55° angulation at head of implant
Implant Prosthetic Diameter	4.07 mm	4.05 mm
Implant Interface	External Hex	External Hex
Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)
Implant Endosseous Surface	Grit-blasted	Grit-blasted
Abutment		
Abutment Design	Non-engaging; Compact conical design	Non-engaging; Compact conical design
Prosthetic Attachment	Screw-retained	Screw-retained
Collar Height	1.5, 2.5, 3.5, 4.5 mm	1.5, 2.0, 3.0, 4.0, 5.5 mm
Collar Diameter	4.6 mm	4.8 mm
Abutment Angle	None (straight only)	None (straight only)
Abutment Material	Unalloyed titanium (ASTM F67) Grade 4; with anodized surface treatment	Titanium alloy (ASTM F136) Grade 5; Titanium Nitride (TiN) coating
Restoration	Multi-unit	Multi-unit

The Indications for Use Statement for the subject device is similar to the primary predicate device K173343, with the difference being the name of the device and the exclusion of removable dental prosthesis support. The limitation in the subject device Indications for Use Statement does not change the risk-based assessment of the subject device, nor does it result in the identification of any new risks or the modification of existing risks for the subject device. The difference limits the restorative options for the subject device implants to fixed prosthetic unit support, forgoing removable prosthetic unit support while maintaining the intended use of the subject device implants as placement of the device into the zygoma for rehabilitation of the edentulous maxilla.

The primary predicate device K173343 is for substantial equivalence of the subject device implant designs. The subject device ZAGA Regular zygomatic implants have a design that is substantially equivalent design to implants in K173343, specifically the Zygan zygomatic implants. Similarly, the subject device ZAGA Advanced zygomatic implants have a design that is substantially equivalent design to implants in K173343, specifically the Oncology and Zygan zygomatic implants, with the only difference being the flat cut into the buccal-face of the implant coronal region. This feature of the ZAGA Advanced zygomatic implant does not negatively impact the mechanical performance of the implant.

The primary predicate device K173343 also serves as the primary predicate for substantial equivalence of the subject device screw-retained abutment designs.

The reference device K163634 is for the substantial equivalence of the subject device screw-retained abutment implant prosthetic diameter, material and surface treatment. The reference device K181703 is for the substantial equivalence of the subject device screw-retained abutment collar diameter, and abutment collar height.

The subject device implants incorporate the same materials and encompass similar ranges of dimensions as the predicate device cleared in K173343. The surface treatment applied to the endosseous threads of the subject device implants is identical to that cleared in K173343. The material and surface treatment applied to the subject device abutments is identical to that of the healing abutments cleared in K163634. All subject device components are for single-patient, single-use, and all are provided sterile. Similarly, the components cleared in the primary predicate K173343 are for single-patient, single-use and are provided sterile.

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 K173343.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing was performed according to ISO 14801. The results from the testing demonstrated fatigue performance of the subject device to be substantially equivalent to that of the primary predicate K173343.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device and the predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. The subject device and the predicate devices are packaged in similar materials and sterilized using similar methods.

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