November 9, 2022

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

Re: K222497
Trade/Device Name: Zaga Zygomatic System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 17, 2022
Received: August 18, 2022

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)*

K222497

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.

510(k) Summary

ZAGA Zygomatic System

Southern Implants (Pty) Ltd

K222497

November 9, 2022

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

PREDICATE DEVICE INFORMATION

The primary predicate device is K192651.

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

The ZAGA zygomatic implants are partially threaded root-form dental implants with an external hexagonal abutment interface angled 55° at the head of the implant, and are threaded internally for attachment of mating abutments. The ZAGA zygomatic implants are provided in two designs: the ZAGA Round zygomatic implant (previously named the ZAGA Regular), coronally and apically threaded, diameter 4.3 mm (coronal) tapering to 3.4 mm (apical), in overall lengths ranging of 30 mm and 60 mm; and the ZAGA Flat zygomatic implant (previously named the ZAGA Advanced), apically threaded, diameter 4.3 mm (coronal) tapering to 3.4 mm (apical), in overall lengths ranging from 30 mm to 60 mm, with a flat cut into the buccal-facing side of the implant body. Only the length 30, 32.5, 57.5 and 60 mm ZAGA Round zygomatic implants and length 55, 57.5 and 60 mm ZAGA Flat zygomatic implants are a subject of this submission.

All ZAGA zygomatic 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 K192651. The subject device implants are manufactured in the same facilities using the same manufacturing processes as used for the Southern Implants predicate device previously cleared in K192651.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility (referenced from K192651); comparison of device dimensions and features; sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 17665-1, ISO TS 17665-2; bacterial endotoxin according to USP 39-NF34; sterile barrier shelf life (referenced from K192651); MR safety evaluation and MR Conditional labeling as per the recommendations of the FDA Guidance Document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"; and static and dynamic compression-bending according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* (referenced from K192651 as the surgical protocol of the implants did not warrant the additional subject device lengths as a new worst-case for fatigue testing).

Non-clinical worst-case MRI review was performed to evaluate the metallic Straumann® ZAGA Zygomatic Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795; and Oriso, Kenta, Takuya Kobayashi, Makoto Sasaki, Ikuko Uwano, Hidemichi Kihara, and Hisatomo Kondo. "Impact of the static and radiofrequency magnetic fields produced by a 7T MR imager on metallic dental materials." Magnetic Resonance in Medical Sciences 15, no. 1 (2016): 26-33), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Clinical data submitted, referenced or relied upon to demonstrate substantial equivalence include: a clinical case report demonstrating the use of 60mm length zygomatic implants in a patient, and two published articles utilizing, among other implants, 60mm length zygomatic implants for patient rehabilitation. These articles are summarized below:

- Parel et al. (Remote implant anchorage for the rehabilitation of maxillary defects. *The Journal of prosthetic dentistry* 86.4 (2001): 377-381) presented a rationale for the use of remote bone sites and zygomatic implants for rehabilitating patients with maxillary defects. Parel et al. provide clinical data on the use of 59 zygomatic implants in lengths ranging from 25 to 60mm.

- Fernández-Ruiz et al. (Evaluation of quality of life and satisfaction in patients with fixed prostheses on zygomatic implants compared with the all-on-four concept: a prospective randomized clinical study. *International Journal of Environmental Research and Public Health* 18.7 (2021): 3426) present a prospective randomized clinical study comparing patient quality of life and satisfaction with their prosthesis on zygomatic implants versus the All-on-Four surgical concept with conventional implants. This study reported 40 zygomatic cases in which zygomatic implants of lengths 35 – 60mm were used.

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:

K192651, ZAGA Zygomatic System, Southern Implants (Pty) Ltd.
A comparison of the technological characteristics of the subject devices and the primary predicate devices is provided in the following table.

Comparison	Subject Device	Primary Predicate Device
	Additional lengths of ZAGA Zygomatic Implant System **Southern Implants (Pty) Ltd**	**K192651** **ZAGA Zygomatic Implant System** **Southern Implants (Pty) Ltd**
Implant		
Indications for Use Statement	Straumann® Zygomatic 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.	Straumann® Zygomatic 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.
Product Code	DZE	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/Reference	Not applicable	Implant design
Implant Design	Partially threaded root-form implants for placement into the zygoma.	Partially threaded root-form implants for placement into the zygoma.
Implant Diameter	ZAGA Round: 4.3 mm (coronal) taper to 3.4 mm (apical) ZAGA Flat: 4.3 mm (coronal with 3.35 mm flat) taper to 3.4 mm (apical)	ZAGA Round: 4.3 mm (coronal) taper to 3.4 mm (apical) ZAGA Flat: 4.3 mm (coronal with 3.35 mm flat) taper to 3.4 mm (apical)
Implant Length	ZAGA Round: 30, 32.5, 57.5, 60 mm ZAGA Flat: 55, 57.5, 60 mm	ZAGA Round: 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55 mm ZAGA Flat: 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5 mm
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	4.07 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
How Provided		
Sterility	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use

The Indications for Use Statement for the subject device is identical to the predicate device K192651.

The primary predicate device K192651 is for substantial equivalence of the subject device implant designs. The subject device implants have the same external hex connection, identical implant diameters, prosthetic platform angulation and diameter, material, endosseous surface, sterility status method, usage and compatible prosthetic components. The clinical evidence, in the form of a clinical case report and two publications, is for the substantial equivalence of the subject device implant lengths (see clinical performance data).

Substantial equivalence of the subject device implants 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 K192651.

In support of substantial equivalence of the additional lengths of ZAGA zygomatic implants in terms of mechanical performance, dynamic compression-bending testing performed according to ISO 14801 are referenced from K192651. Dynamic testing (referenced from K192651) was performed on worst-case subject device constructs. The additional lengths of the ZAGA zygomatic implants does not influence the results of this fatigue testing and so additional fatigue testing was not warranted for this submission. The results from the testing provided in K192651 are thus valid for the subject devices and demonstrates the fatigue performance of the subject device exceeds its indication.

CONCLUSION

The subject device and the predicate device have the same intended use and indications for use, have similar technological characteristics, and are made of the same materials. The subject device and the predicate device encompass a similar range of physical dimensions, including the same diameter of the implants, same prosthetic platform and same compatible abutment range. The differing total lengths of the subject device is supported by clinical data provided. The subject device and the predicate devices are packaged in similar materials and sterilized using the same methods.

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