December 5, 2019

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

Re: K191250
Trade/Device Name: Southern Implants PEEK Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 6, 2019
Received: September 10, 2019

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)*
K191250

Device Name
Southern Implants PEEK Abutments

Indications for Use *(Describe)*
The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

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

Sponsor:

Company Name: Southern Implants (Pty) Ltd.

Company Address: 1 Albert Road
Irene,
0062
South Africa

Telephone: + 27 12 667 1046

Fax: + 27 72 313 5715

Contact Person: Lauranda G. Breytenbach

Summary Preparation Date: May 7, 2018

Device Name:

Trade Name: Southern Implants PEEK Abutments

Common/Usual Name: PEEK Abutments

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: 21 CFR 872.3630

Product Codes: NHA

Device Class: Class II

Predicate Devices:

Predicate #	Manufacturer	Device Name	K Number
Primary Predicate	Southern Implants (Pty) Ltd	Southern Implants PEEK abutments	K172160

Device Description:

The Southern Implants PEEK abutments are endosseous dental implant abutments. The PEEK abutments are available in a variety of preformed and customized forms. The PEEK abutments are available as temporary abutments.

Temporary abutments are used as an aid in manufacturing a temporary prosthesis for prosthetic rehabilitation. They are used for direct connection to an endosseous implant. Temporary abutments are available in a 2 mm collar direct to implant.

These abutments are made from white PEEK (ASTM F2026).

The PEEK abutments are premanufactured and are available in a variety of connections, engaging and non-engaging, to suit the implant systems manufactured by Southern Implants.

Titanium retaining screws are also available to use with the PEEK abutments.

Indications for Use

The Southern Implants PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Equivalence to Predicates

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:

K172160, Southern Implants PEEK Abutments

Tables comparing the subject device and primary predicate devices is provided below.

Device and Manufacturer	New device	Primary Predicate (K172160)
	Southern Implants PEEK abutments	Southern Implants PEEK abutments
Product Code	PKIP2H; PKIP2NH; PKC-M-2; PKC-NM-2	PKBN2H; PKBN2NH; PKB2H; PKB2NH; PKBA2H; PKBA2NH; PKBBB2H; PKBBB2NH; PKMAX9-2H; PKMAX9-2NH; PKC-EL-35-2; PKC-NL-35-2; PKC-EL-43-2; PKC-NL-43-2; PKC-EL-50-2; PKC-NL-50-2; PKC-EL-60-2; PKC-NL-60-2; PKC-DC3-2; PKC-NDC3-2; PKC-DC4-2; PKC-NDC4-2; PKC-DC5-2; PKC-NDC5-2; ITS6-PKC1; ITS-PKC1; PKC-MC; PKC-MCW.
Indications for Use	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly	The Southern Implants PEEK Abutments are premanufactured prosthetic components directly

	connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.	connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.
Intended Use	Temporary Abutment	Temporary Abutment
Material	Polyetheretherketone (PEEK)	Polyetheretherketone (PEEK)
Colour	White	White
Attachment Method	Screw retained Engaging and Non-Engaging	Screw retained Engaging and Non-Engaging
Duration of use	180 days, single use	180 days, single use
Implant/Abutment Connection	External Hex Internal Hex	Southern Implants MAX External Hex Tri-Nex Deep Conical Internal Hex Internal Taper Compact Conical
Height (mm)	14.5	9-14.5
Collar height (mm)	2	1-2
Diameter (mm)	3.35 – 4.00	3.35 – 7.35
Abutment Profile	Cylinder with retention feature	Cylinder with retention feature
Sterility	Sterile	Sterile

The Southern Implants PEEK abutments are substantially equivalent to predicate device in:

- Indications for Use
- Intended Use
- Material
- Colour
- Attachment Method
- Duration of Use
- Implant/Abutment Connection
- Height
- Collar height
- Diameter
- Abutment Profile
- Sterility

The Southern Implants PEEK Abutments are delivered to the patients sterile and can be user sterilized if required.

Nonclinical Testing and Performance Testing

Non-clinical testing data provided or referenced to demonstrate substantial equivalence included:

The sterilization method is Gamma radiation and has been validated in accordance with ISO 11137.

The proposed user sterilization method is steam sterilization and is validated in accordance with ISO 17665.

Packaging was validated in accordance with ISO 11607. Accelerated aging per ASTM-F-1980 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 predicate, has the same intended use, and the same patient contact type and duration. The subject devices are biocompatible in accordance with ISO 10993-1.

The subject device shown no cytotoxicity when tested in accordance with ISO 10993-5.

Clinical Studies

No clinical studies were conducted.

Final Conclusion

Substantial equivalence has been shown for Southern Implants PEEK Abutments.