DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 1, 2016

Southern Implants
% Ms. Yolanda Smith
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K161548
Trade/Device Name: Osseointegrated Fixtures
Regulation Number: 21 CFR 878.3680
Regulation Name: Nose Prosthesis
Regulatory Class: Class II
Product Code: FZE
Dated: November 1, 2016
Received: June 3, 2016

Dear Ms. Smith:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161548

Device Name
Osseointegrated Fixtures

Indications for Use *(Describe)*
Southern Implants Osseointegrated Fixtures are indicated for the attachment of an external aesthetic restoration prosthesis for the restoration of a physical defect when other means of attachment are inadequate. The endosseous implant provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).

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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SECTION 5 – 510(k) Summary

Submitter

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Contact person

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Date prepared: December 1, 2016

Name of the device

Trade name:	Osseointegrated Fixtures
Common name:	Implants for prosthetic retention External
Classification name:	Nose prosthesis
Regulation Number	21 CFR 878.3680
Product Code:	FZE
Device Class:	Class II

Legally marketed devices to which equivalence is claimed (predicate devices)

Manufacturer	Device Name	K Number
NSI, Inc. (Manufactured by Southern Implants)	NSI Hexed and Non-Hexed Implant System	K020617
NSI, Inc. (Manufactured by Southern	NSI Hexed and Non-Hexed Implant System	K003620
Nobel Biocare	Nobel Biocare Endosseous Implants (Maxillofacial Indications)	K090630
Straumann USA	Straumann Extraoral Implant System	K990458

Device Description

The device 'Osseointegrated Fixtures' refers to a system involving endosseous implants and their accessories. The endosseous implants are solid, screw-type, self-tapping implants made from commercially pure titanium, with the same enhanced surface as the Southern Implants dental implants. The accessories include drills to prepare the site, abutments and attachments to aid the prosthetic retention, placement tools, instruments and laboratory components.

Indications for Use

Southern Implants Osseointegrated Fixtures is indicated for the attachment of an external aesthetic restoration prosthesis for the restoration of a physical defect when other means of attachment are inadequate. The endosseous implant provides the bone anchorage for the prosthetic attachment. These devices are indicated for use in the maxillo-craniofacial region (including ear, nose and eye).

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Intended use

The implants are placed in bone and are intended to osseointegrate to provide an attachment for an external aesthetic restoration prosthesis. The device provides a solution for the prosthetic restoration of a cosmetic defect when other means (such as adhesives or suction) are inadequate to retain the prosthesis.

COMPARISON OF TECHNICAL CHARACTERISTICS

Substantial equivalence

This device and the predicates are all used in the same way: they are screwed into bone where they are intended to osseointegrate to provide an attachment for a prosthesis. The material for all implants is titanium and the operating principle which is primary fixation by means of an external thread, and permanent fixation by osseointegration are the same. Torque for placement is transferred through the connection interface in the implants. Osseointegration is enhanced by means of a moderately rough titanium surface

In comparison to predicates NSI Hexed and Non-Hexed Implant System (K020617 & K003620) are indicated for the attachment of dental prosthetics, and the Southern Implants Osseointegrated Fixtures are used to attach extraoral cosmetic prosthetics. Thus, it will not be subject to the kind of loads experienced by dental implants. Additionally, the extraoral environment is typically biologically cleaner than the oral environment.

The Nobel Biocare Endosseous Implants (Maxillofacial Indications) (K090630) and Straumann Extraoral Implant System are indicated for the attachment of an external aesthetic restoration prosthesis in the maxillofacial/craniofacial region. In comparison, the use of the Southern Implants Osseointegrated Fixtures is not restricted to the craniofacial region. However, its use remains the same, for the mechanical retention of a cosmetic prosthesis. This device enables other external aesthetic prosthetic restorations which would benefit from the availability of bone-anchorage in the same way as maxillofacial/craniofacial prostheses do.

After safety and testing was performed, Southern Implants has concluded that the device does not introduce any significant questions of safety and efficacy and is substantially equivalent to the predicate devices.

Safety Testing

Standard	Standard Title
ISO 11137-1	Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation & Routine Control of a Sterilization Process for Medical Devices
ISO 11137-2	Sterilization of Health Care Products – Radiation – Part 1: Establishing the Sterilization Dose
ISO 11737-1	Sterilization of Medical Devices – Microbiological Methods – Part 1: Estimation of Population of Microorganisms on Products
ISO 11737-2	Sterilization of medical devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Validation of a Sterilization Process
EN 556-1	Sterilization of Medical Devices - Requirements for Medical Devices to be designated

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	"STERILE" - Part 1: Requirements for Terminally Sterilized Medical Devices
ISO 10993-1	Biological evaluation of medical devices- part 1: Evaluation and testing within a risk management process
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
ISO 10993-5	Biological evaluation of medical devices – Part 5; Tests for *in vitro* cytotoxicity
ISO 10993-18	Biological evaluation of medical devices – Part 18: Chemical characterization of materials.
ISO 11607-1	Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)
ISO 11607-2	Packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)]. (Sterility)
ASTM D4169-14	Standard practice for performance testing of shipping containers and systems. (Sterility)
ASTM F1929-12	Standard test method for detecting seal leaks in porous medical packaging by dye penetration. (Sterility)
ASTM F88/F88M-09	Standard test method for seal strength of flexible barrier materials. (Sterility)
ASTM F1980-07	Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)
ISO 5832-3:1996	Implants for surgery -- metallic materials -- part 3: wrought titanium 6-aluminium 4-vanadium alloy. (Materials)
ASTM F136-13	Standard specification for wrought titanium-6 aluminum-4 vanadium ELI (extra low interstitial) alloy for surgical implant applications (Uns R56401). (Materials)
ASTM F67-13	Standard specification for unalloyed titanium for surgical implant applications (Uns R50250, Uns R50400, Uns R50550, Uns R50700). (Materials)
IEC 62366-1	Medical devices - part 1: application of usability engineering to medical devices. (General I (QS/RM))
ISO 14644-1	Cleanrooms and associated controlled environments - part 1: classification of air cleanliness. (Sterility)
ISO 15223-1	Medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements. (General I (QS/RM))
BS EN 1041	Information supplied by the manufacturer of medical devices
ASTM F899-12b	Standard Specification for Wrought Stainless Steels for Surgical Instruments

CONCLUSION

The technological characteristics of this device and its predicates are substantially equivalent. They are all composed of commercially pure titanium, with a moderately rough surface for osseointegration. They are all self-tapping, screw-type implants. They all have similar systems of drills, abutments, placement tools and prosthetic aids. After safety testing was performed, Southern Implants has concluded that the device does not introduce any significant questions of safety and efficacy and is substantially equivalent to the predicate devices.