DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 26, 2017

Silony Medical GmbH
℅ Mr. Richard Vincins
Vice President, QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K162587
Trade/Device Name: ROCCIA® ACIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 23, 2016
Received: December 28, 2016

Dear Mr. Richard Vincins:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K162587

Device Name
ROCCIA® ACIF

Indications for Use *(Describe)*
The ROCCIA ACIF is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ROCCIA ACIF is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 to T1. The System is intended to be used with supplemental fixation; the ROCCIA ACIF device is required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

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

ROCCIA® ACIF

K162587

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Richard A. VINCINS, Vice President, QA/RA

Email: project.management@emergogroup.com

3. Date Prepared

25 January 2017

4. Device Identification

Trade/Proprietary Name: ROCCIA® ACIF

Common/Usual Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device

Regulation Number:	888.3080
Product Code:	ODP, Intervertebral Fusion Device with Bone Graft, Cervical
Device Class:	Class II
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device

Primary Predicate: K150362, NuVasive CoRoent Small Interbody System, NuVasive Incorporated

6. Device Description

The ROCCIA ACIF was developed for primary stabilization and restoration of the cervical spine. Treatment is carried out using anterior cervical discectomy and fusion (ACDF) surgery for patients with symptomatic degenerative disc problems. The system as a cage design improves interbody fusion as its generously proportioned design allows for the insertion of either bone or bone substitute materials. At the same time, the cage has a broad supporting surface that largely prevents sinking when implanted correctly.

The ROCCIA ACIF Cage is manufactured from PEEK material. The cage has a large cylindrical hollow in the middle which can be filled with bone material or bone substitute material. The large volume of filling material is in direct contact with the patient's vertebra and supports the fusion of the cage with the bone. The load transmission from the vertebra to the cage is effected via a solid frame construction around the hollow recess. The base and cover plates of the cage have a serrated surface which supports the primary anchorage of the cage.

The cage is available in two different versions: a wedge-shaped version and an anatomic version. The design of the upper and lower surface of the cage corresponds to the shape of the respective opposite surface of the intervertebral disc. The upper surface component of the anatomic cage is convex, while the lower side is aligned straight in order to match the natural anatomy of the end plate. The four (4) titanium markers project from the surface of the cage above and below and penetrate into the vertebrae when the cage is inserted. This penetration serves for preliminary fixation of the cage. The markers furthermore support the location and verification of correct positioning of the cage on the X-ray images. This positioning is additionally supported by two integrated horizontal titanium marker pins.

The ROCCIA instrumentation is ergonomically appropriate and designed as modular components. The ROCCIA insertion device enables the user to perform various instrumentation steps with just a single instrument. The instruments are designed to be used with the ROCCIA ACIF, and are made of materials common for medical devices used in implantable device instrumentation tools. The instruments are intended to be cleaned, sterilized, and reused for the purposes of the multiple implantation procedure.

The ROCCIA ACIF Cage is manufactured from PEEK conforming to ASTM F2026 and the titanium markers are manufactured from Ti6Al4V ELI, conforming to ASTM F136. The ROCCIA instrumentation is manufactured from stainless steels conforming to ISO 16061 and ASTM F898.

7. Indication for Use Statement

The ROCCIA® ACIF is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ROCCIA ACIF is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 to T1. The System is intended to be used with supplemental fixation; the ROCCIA ACIF device is required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

8. Substantial Equivalence Discussion

The ROCCIA ACIF has been shown to be substantially equivalent to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of ROCCIA ACIF and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Silony Medical completed a number of non-clinical performance tests. The ROCCIA ACIF meets all the requirements for overall design, sterilization, biocompatibility, and performance testing results confirming that the design output meets the design inputs and specifications for the device.

The ROCCIA ACIF passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Mechanical Load Testing – Passed the requirements required by standards ASTM 2077 and ASTM 2267 for static axial compression, static compression, static axial torsional, cyclic compression, and cyclic torsion
- Mechanical Load Testing Aged – After placing product for one (1) year and five (5) year aging, passed the requirements for standard ASTM 2077 for cyclic compression
- Finite Element Analysis – Comparison performed with subject device and predicate device showed acceptable results as compared to the predicate device
- Subsidence Behavior Testing – Comparison performed with subject device and predicate device showing comparable results
- Static Expulsion Testing – Comparison performed with subject device and predicate device showing comparable results
- Biocompatibility – Biological evaluation was performed on known materials supporting that no toxic substances or materials are used; materials used in marketed implant devices

- Cleaning and Sterilization Testing – Passed the requirements for sterilization validation for irradiation to ISO 11137 meeting an SAL of 10^{-6} and cleaning validation passed the established requirements
- Shelf Life Testing – Packaging and shelf life were validated for a 5 years
- Storage and Transport Testing – Shipping and transport validation supported there were no adverse effects to the product packaging and remained in a sterile state

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The ROCCIA ACIF, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).