December 21, 2017

Silony Medical GmbH
% Indraj Bamrah
Senior Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K171434
Trade/Device Name: ROCCIA® MultiLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: November 30, 2017
Received: December 4, 2017

Dear Indraj Bamrah:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171434

Device Name
ROCCIA® MultiLIF

Indications for Use *(Describe)*
The ROCCIA® MultiLIF is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA® MultiLIF implants are intended for use in interbody fusions at one or two contiguous levels in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic disc degeneration (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

The ROCCIA® MultiLIF implants are intended for use at one or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The ROCCIA® MultiLIF implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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® MultiLIF

K171434

1. Submission Sponsor

Silony Medical GmbH

Leinfelder Straße 60

70771 Leinfelden-Echterdingen

GERMANY

Phone number: +49 711 78 25 25 40

Contact: Bircan TASDELEN

Title: Head of Quality Management and Regulatory Affairs

2. Submission Correspondent

Emergo Global Consulting, LLC

2500 Bee Cave Road

Building 1, Suite 300

Austin, TX 78746

Office Phone: (512) 327.9997

Contact: Indraj Bamrah, Senior Regulatory Consultant

Email: project.management@emergogroup.com

3. Date Prepared

December 19, 2017

4. Device Identification

Trade/Proprietary Name: ROCCIA® MultiLIF

Common/Usual Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Body Fusion Device

Regulation Number:	888.3080
Product Code:	MAX, Intervertebral Fusion Device with Bone Graft, Lumbar
	PHM, Intervertebral Fusion Device with Bone Graft, Thoracic
Device Class:	Class II
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device

Primary Predicate: K153419, NuVasive® CoRoent® Thoracolumbar System, NuVasive, Incorporated.

6. Device Description

The ROCCIA MultiLIF cage is manufactured from Ti6Al4V ELI alloy. The cage has a large cylindrical hollow in the middle which can be filled with bone material. The cage has numerous threaded holes that allow for correct placement of the cage.

The ROCCIA MultiLIF cage is available in a range of sizes to accommodate individual patient pathology and anatomical conditions.

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 MultiLIF, 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 future implantation procedures.

The ROCCIA MultiLIF cage is manufactured from Ti6Al4V ELI alloy conforming to ASTM F136. The ROCCIA instrumentation is manufactured from stainless steels conforming to ISO 16061 and ASTM F899.

7. Indications for Use Statement

The ROCCIA® MultiLIF is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA® MultiLIF implants are intended for use in interbody fusions at one or two contiguous level~~s~~ in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), following discectomy for

the treatment of a symptomatic disc degeneration (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

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The ROCCIA® MultiLIF implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

8. Substantial Equivalence Discussion

The ROCCIA MultiLIF has 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 MultiLIF and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Silony Medical GmbH completed a number of non-clinical performance tests. The ROCCIA MultiLIF is substantially equivalent to predicate devices.

The ROCCIA MultiLIF 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 – Comparison performed with subject device and predicate device showing comparable results when tested in accordance with ASTM F2077.
- Subsidence Behavior Testing – Comparison performed with subject device and predicate device showing comparable results when tested in accordance with ASTM F2267.
- Static Expulsion Testing – Comparison performed with subject device and predicate device showing comparable results when tested.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use are 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 has different technological characteristics but design control activities show that the differences do not raise new questions of safety and effectiveness when compared to the predicate. Based on the comparison and analysis above, the ROCCIA MultiLIF is determined to be substantially equivalent to the referenced predicate device.