Silony Medical GmbH
% Ms. Meredith May
Vice President
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

July 11, 2018

Re: K180963
Trade/Device Name: ROCCIA® TLIF and ROCCIA® ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: March 5, 2018
Received: April 12, 2018

Dear Ms. May:

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 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,

Brent Showalter -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)*
K180963

Device Name
ROCCIA® TLIF and ROCCIA® ALIF

Indications for Use *(Describe)*

The ROCCIA TLIF and ROCCIA ALIF Cage 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 device is to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA TLIF Cage 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 TLIF and ROCCIA ALIF Cage 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 TLIF Cage 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

ROCCIA® TLIF AND ROCCIA® ALIF

1. **Submission Sponsor**

Silony Medical GmbH
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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**

Contact: Meredith May, MS, RAC
Phone number: 719-337-7579
Email: MeredithMay@EmpiricalConsulting.com

3. **Date Prepared**

05-Apr-2018

4. **Device Identification**

Trade/Proprietary Name:	ROCCIA® TLIF and ROCCIA® ALIF
Common/Usual Name:	Intervertebral Fusion Device
Classification:	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. **Predicate Devices**

Primary Predicate: K171434, ROCCIA® MultiLIF Cage, Silony Medical
Additional Predicate: K141217, AccuLIF® TL and PL Cage, Stryker
Additional Predicate: K072253, SynFix-LR, Synthes
Additional Predicate: K151214, ALIF Interfixed System, NuVasive®
Additional Predicate: K153720, ENZA Zero-Profile Anterior IBFD, Camber Spine

6. Device Description

The ROCCIA® Transforaminal Lumbar Interbody Fusion (ROCCIA® TLIF) and ROCCIA® Anterior Lumbar Interbody Fusion (ROCCIA® ALIF) cages are implants for the primary stabilization and restoration of the physiologic lordosis of the lumbar and thoracic spine. Subject device implants are manufactured from Titanium Alloy Ti6Al4V ELI per ASTM F136. The ROCCIA® TLIF and ROCCIA® ALIF cages are offered in a variety of sizes to facilitate a variety of patient anatomies.

The ROCCIA® instrumentation is ergonomically appropriate and designed as modular components. The instruments are designed to be used with the ROCCIA® Transforaminal Lumbar Interbody Fusion (TLIF) and ROCCIA® Anterior Lumbar Interbody Fusion (ALIF), and are made of materials commonly used to manufacture medical device instruments. The instruments are intended to be cleaned, sterilized, and reused for the purposes of future implantation procedures.

7. Indications for Use

The ROCCIA TLIF and ROCCIA ALIF Cage 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 device is to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA TLIF Cage 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 TLIF and ROCCIA ALIF Cage 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 TLIF Cage implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

8. Substantial Equivalence Discussion

ROCCIA® TLIF and ROCCIA® ALIF cages has shown to be substantial equivalent to the predicate devices with respect to principles of operation, indications for use, materials of manufacture, implant size range, sterility.

9. Non-Clinical Performance Data

The ROCCIA® TLIF and ROCCIA® ALIF cages has been tested in the following test modes:

- Static axial compression per ASTM F2077-11
- Static shear compression per ASTM F2077-11
- Dynamic axial compression per ASTM F2077-11
- Dynamic compression-shear per ASTM F2077-11
- Static Subsidence per ASTM F2267-04
- Static Expulsion per S-01:2013

The results of this non-clinical testing demonstrates the substantially equivalent mechanical performance of the ROCCIA® TLIF and ROCCIA® ALIF as compared to legally marketed predicate devices.

10. Statement of Substantial Equivalence

Based on the comparison and analysis above, the ROCCIA® TLIF and ROCCIA® ALIF cages are determined to be substantially equivalent to the referenced predicate devices.