Silony Medical GmbH
℅ Ms. Meredith May
Vice President
Empirical Consulting LLC
4628 Northpark Dr.
Colorado Springs, Colorado 80918

June 13,2019

Re: K182608
Trade/Device Name: Oyster ACIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 13, 2019
Received: May 14, 2019

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. 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 Melissa Hall
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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 on last page.

510(k) Number *(if known)*
K182608

Device Name
Oyster ACIF Cage

Indications for Use *(Describe)*

The Oyster ACIF Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Oyster ACIF Cage 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 Oyster ACIF Cage 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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K182608 - 510(K) SUMMARY

Submitter's Name:	Katharina Barsch Silony Medical GmbH
Submitter's Address:	Leinfelder Straße 60 Leinfelden-Echterdingen, Germany D-70771
Submitter's Telephone:	+49 711 78 25 25 40
Additional Contact Person:	Meredith Lee May MS, RAC Empirical Consulting 719.337.7579 MMay@EmpiricalConsulting.com
Date Summary was Prepared:	18 Sep 2018
Trade or Proprietary Name:	Oyster ACIF Cage
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Abdominal and Surgical Devices Branch (ASDB)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Oyster cages are Cervical Interbody Fusion cages and have been developed for at up to two contiguous levels from C2 to T1. It is intended for insertion between two adjacent cervical vertebrae. The implants are offered in heights from 4 to 10mm, and 3 footprints (14mm x 15mm, 16mmx17mm, 14mmx17mm). The implants are manufactured by SLM and standard milling process.

INDICATIONS FOR USE

The Oyster CIF Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Oyster CIF Cage 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 Oyster CIF Cage 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.

TECHNOLOGICAL CHARACTERISTICS

Oyster ACIF Cage is made from Ti6Al4V ELI (Grade 23). The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Materials of manufacture

- Structural support mechanism
- Manufacturing methods

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K162587	ROCCIA® ACIF	Silony Medical GmBH	Primary
K172888	EIT Cellular Titanium® Cervical Cage	EIT Emerging Implant Technologies GmbH	Additional

PERFORMANCE DATA

The Oyster ACIF Cage has been tested in the following test modes:

- Static Axial Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Static Torsion per ASTM F2077
- Dynamic Axial Compression per ASTM F2077
- Dynamic Compression Shear per ASTM F2077
- Dynamic Torsion per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the Oyster ACIF Cage is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Oyster ACIF Cage is substantially equivalent to the predicate device.