Silony Medical GmbH
Melanie Lubjuhn
Team Leader Regulatory Affairs
Leinfelder StraBe 60
70771 Leinfelden-Echterdingen
Germany

July 18, 2019

Re: K190680
Trade/Device Name: Favo® S-TLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, PHM
Dated: May 20, 2019
Received: May 23, 2019

Dear Melanie Lubjuhn:

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 below.

510(k) Number *(if known)*
K190680

Device Name
FAVO® S-TLIF

Indications for Use *(Describe)*
The FAVO S-TLIF 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 FAVO S-TLIF Cage is 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 FAVO S-TLIF Cage is 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 FAVO S-TLIF Cage 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

FAVO® S-TLIF

K190680

1. Submission Sponsor

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Contact: Melanie LUBJUHN
Title: Team Leader Regulatory Affairs

2. Submission Correspondent

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Contact: Melanie LUBJUHN
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Email: MLubjuhn@silony-medical.com

3. Date Prepared

14th March 2019

4. Device Identification

Trade/Proprietary Name:	FAVO S-TLIF
Common/Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Lumbar Intervertebral Body Fusion Device with Bone Graft, Thoracic
Regulation Number:	888.3080
Product Code:	MAX, PHM
Device Class:	II
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device

Primary Predicate Device

K180963, ROCCIA® TLIF Cage, Silony Medical GmbH

Additional Predicate Device

K172888; EIT Cellular Titanium TLIF Cage, EIT Emerging Implant Technologies GmbH

6. Device Description

The FAVO S-TLIF (straight transforaminal lumbar interbody fusion) Cage is an implant for primary stabilization and restoration of physiological lordosis in the lumbar and thoracic spine. The cage is designed for transforaminal approaches.
The aim is to eliminate discogenic back pain, correct deformities, remedy instabilities, restore intervertebral height, restore physiological lordosis, and provide biomechanical support for bone fusion in the disc space.
The system is designed for use with autogenous bone graft to facilitate fusion and must be used with additional stabilization. For posterior lumbar stabilization, Silony Medical recommends the use of a posterior spinal fixator (e.g., the VERTICALE system). The devices are to be used in patients who have had at least six months of non-operative treatment. The FAVO S-TLIF is manufactured from titanium alloy conforming to ASTM F136 / ISO 5832-3 and ASTM F3001.
The FAVO S-TLIF implant is delivered in a sterile condition and can be used without any further preparations. The cages are packaged in accordance with EN ISO 11607 Party 1+2 and sterilized with gamma irradiation at a minimum dose of 25 kGy.
Implants delivered by the manufacturer in a sterile condition may not be sterilized.

7. Indication for Use Statement

The FAVO S-TLIF 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.

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8. Substantial Equivalence Discussion

The FAVO S-TLIF has shown to be substantial equivalent to the predicate device mentioned in chapter 5 of this section with respect to indications for use, principles of operations, technological characteristics, materials, and performance testing.

9. Non-Clinical Performance Data

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

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

- Mechanical performance according
    - ASTM F2077 for Test Methods for Intervertebral Body Fusion Devices (static axial compression, static compressive share, dynamic axial compression and dynamic compressive share)
    - ASTM F2267 for Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- Static expulsion behavior
- Biocompatibility according ISO 10993-1
- Cleaning and Sterilization Testing according ISO 11137
- Shelf Life Testing for 10 years
- Storage and Transport Testing

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. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

The FAVO S-TLIF is determined to be substantially equivalent to the referenced predicate device(s).