Renovis Surgical Technologies Inc.
% Sharyn Orton
Senior Consultant
MEDIcept. Inc.
200 Homer Ave
Ashland, Massachusetts 01721

June 14, 2018

Re: K180502
Trade/Device Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: May 15, 2018
Received: May 16, 2018

Dear Dr. Orton:

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,

Melissa Hall -S
2018.06.14 12:57:33 -04'00'

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)*
K180502

Device Name
S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use *(Describe)*
The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K180502

A) Submitted by:
Renovis Surgical Technologies Inc.
1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374
Phone: 909-557-2360
Fax: 909-307-8571

Official Contact:
Anthony DeBenedictis
Vice President of Quality Assurance

Consultant:
Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

B) Classification Name: Intervertebral Fusion Device, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II

Regulations and Product Code: 21 CFR 888.3080
OVD

Classification panel: Orthopedic

C) Predicates: Primary: K140106 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
K131122 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

D) Date Prepared: June 12, 2018

E) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is FDA cleared as K131122 and K140106 (sterile implants). This application describes additional cages offerings (new lengths, widths, and lordosis) and a packaging change.

The S128 ALIF System includes cages of a variety of lengths, widths, heights, and lordosis to suit the individual pathology and anatomical conditions of the patient. The different shape of the footprint allows for different surgical approaches for insertion. S128 ALIF System cages are standalone for devices <20º when implanted with the coverplate and screws. Implants are offered in Ti6Al4V and PEEK with Tantalum marker pins. Titanium cages are additively manufactured then machined to the final cage dimensions. PEEK implants are manufactured using traditional methods.

- The Ti6Al4V conforms to the chemical and mechanical requirements of ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- The PEEK is compliant with ASTM F2026-17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.The Tantalum is compliant with ASTM F560-17 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications.

The S128 ALIF System cages that are the subject of this application are gamma sterilized.

The system also includes instruments to allow for implant determination, trialing and disc preparation. Instruments are manufactured from stainless steel in compliance with ASTM A564/M564-13e1 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes.

F) Intended Use/Indications For Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°.

G) Substantial Equivalence Comparison and Discussion

The modified cages have the same Indications for Use, are manufactured from the same materials using the same manufacturing processes, and are gamma sterilized the same as the K140106 predicate cages. The new cages are different sizes and lordosis from the predicate cages.

The manufacturing change was validated.

The new changes were assessed for risk and tested under Design Controls. Successful testing included:

- Dynamic Shear Compression strength testing per ASTM F2077-14
- Expulsion testing

Conclusion: Testing demonstrated that the new S128 ALIF System cages are substantially equivalent to the FDA cleared predicate S128 ALIF System cages.

H) Compliance with Design Controls

All changes were assessed for risk and successfully tested under Design Controls.

I) Compliance with Standards or FDA Guidance

The Renovis S128 ALIF System complies with the following:

- ASTM F2077-14: Test Methods For Intervertebral Body Fusion Devices
- AAMI/ANSI ST72:2011/(R)2016 Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
- AAMI/ANSI/ISO 11137-2:2013 Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose
- AAMI/ANSI/ISO 11137-1:2006/(R)2010 Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control Of A Sterilization Process For Medical Devices [Including: Amendment 1 (2013)]
- AAMI/ANSI/ISO 10993-1:2009/(R)2013 Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within a Risk Management Process
- ISO 17665-1 1st Edition 2006-08-15 Sterilization Of Health Care Products - Moist Heat - Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 2007

Conclusion

There are no new or different issues of safety or effectiveness associated with the new cages or packaging when compared to a predicate device. Testing, where applicable, was verified under Design Controls and found to be acceptable.

The new S128 ALIF System cages are substantially equivalent to the predicate cages.