September 11, 2018

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

Re: K181655
Trade/Device Name: Renovis S180 Lateral Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 9, 2018
Received: July 10, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Melissa Hall -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)*
K181655

Device Name
Renovis S180 Lateral Lumbar Interbody Fusion System

Indications for Use *(Describe)*
The Renovis S180 Lateral Lumbar Interbody Fusion 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). Patients should be skeletally mature and have at least six months of non-operative treatment prior to treatment with the devices.
The Renovis S180 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine. Renovis S180 System implants are to be used with autogenous bone graft.

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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Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K181655

A) Submitted by: Renovis Surgical Technologies
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Official Contact: Anthony DeBenedictis
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Consultant: Sharyn Orton, Ph.D.
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200 Homer Ave
Ashland, MA 01721

B) Classification Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: Renovis S180 Lateral Lumbar Interbody Fusion System

Device Class: Class II

Regulations and Product Code: 21 CFR 888.3080
MAX

Classification panel: Orthopedic

C) Predicates:

- Primary: K170888 Renovis S141 Lumbar Interbody Fusion System
- K131122 Renovis S128 Anterior Lumbar Interbody Fusion System
- K140106 Renovis S128 Anterior Lumbar Interbody Fusion System

D) Date Prepared: September 10, 2018

E) Device Description:

The Renovis S180 Lateral Lumbar Interbody System is an additional offering to the Renovis system of interbody fusion devices.

This application describes changes in lengths, widths, heights and lordosis configurations; material standard; packaging; and additive manufacturing device.

The S180 LLIF 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 a lateral surgical approach for insertion.

The S180 LLIF System cages are manufactured from Ti6Al4V compliant with ASTM F2924 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion.

The system also includes instruments which are manufactured from:

- Stainless steel in compliance with:
    - ASTM F564/A564M – 13e1 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- Ti-6Al-4V in compliance with:
    - ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
    - ASTM F1472-14 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications

F) Intended Use/Indications For Use:

The Renovis S180 Lateral Lumbar Interbody Fusion 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). Patients should be skeletally mature and have at least six months of non-operative treatment prior to treatment with the devices.

The Renovis S180 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine. Renovis S180 System implants are to be used with autogenous bone graft.

G) Substantial Equivalence Comparison and Discussion

The S180 cages have the same clinical Indications for Use, are functionally the same, have a porous structure applied to the superior and inferior surface area, are additively manufactured from Ti-6Al-4V, and are gamma sterilized like the predicate devices.

The S180 cages include different heights, widths, lengths and lordosis; and a change to the additive manufacturing machine. The manufacturing change was validated.

The S180 LLIF System cages are substantially equivalent to the predicate devices.

H) Performance Testing – Bench

Successful mechanical/functional testing of the new worst-case S180 LLIF cages was conducted as follows:

- Dynamic axial compression testing in accordance with ASTM F2077
- Expulsion, static push-out, testing
- Mechanical Tensile Testing per ASTM E8/E8M-15a methods

Sterilization validation was conducted.

I) Compliance with Standards or FDA Guidance

The Renovis S180 LLIF System cages comply with the following:

- ISO 11607-2:2006 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation requirements for forming, sealing and assembly processes
- ISTA 2A:2011 Packaged-products weighing 150 lbs. (68kg) or less
- ASTM D4169:2016 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM E8/E8M-15a Standard Test Methods for Tension Testing of Metallic Materials
- ASTM F2924-14 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
- ASTM F1044-05 (R)2017e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147-05 (R)2017e1 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings
- ASTM F1160-14 (R)2017e1 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- ASTM F1854-15 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM F1978-17 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F2077-17 Test methods for intervertebral body fusion devices
- AAMI/ANSI ST72:2011 Bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing
    - Same as AAMI/ANSI ST72:2011(R)2016
- AAMI/ANSI/ISO 10993-1:2009(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- AAMI/ANSI/ISO 10993-5:2009(R)2014 Biologic Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity
- AAMI/ANSI/ISO 11137-2:2013 Sterilization of health care products - radiation - part 2: establishing the sterilization dose

- AAMI/ANSI/ISO 11737-1:2006 R(2011)Sterilization of health care products - microbiological methods - part 1: determination of the population of microorganisms on product
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components

- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 2007
- Guidance for Industry and FDA Staff – Technical Considerations for Additive Manufactured Medical Devices, December 2017
- Guidance for Industry and FDA Staff – Reporting of Computational Modeling Studies in Medical Device Submissions, September 2016

Conclusion

There are no different issues of safety or effectiveness associated with the S180 LLIF System cages. Testing, where applicable, was conducted found to be acceptable. The S180 LLIF System cages are substantially equivalent to the predicate devices and are expected to perform per their intended use.