DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

August 8, 2017

Re: K170888
Trade/Device Name: Renovis S141 Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 23, 2017
Received: June 26, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170888

Device Name
Renovis S141 Lumbar Interbody Fusion System

Indications for Use *(Describe)*

The Renovis S141 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). Renovis S141 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 S141 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

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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RENOVIS

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K170888

A) Submitted by: Renovis Surgical Technologies
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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 With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: Renovis S141 Lumbar Interbody Fusion System

Device Class: Class II

Regulations and Product Code: 21 CFR 888.3080
MAX

Classification panel: Orthopedic

C) Primary Predicate: K143125 Renovis S141 Lumbar Interbody Cage System
Additional Predicate: K150481 K2M Cascadia

D) Date Prepared: June 23, 2017

E) Device Description:

The Renovis S141 Lumbar Interbody Cage System is FDA cleared as K143126. This application describes a manufacturing change to the K143126 S141 Ti6Al4Vcages; internal dimensional changes; additional cages geometries; and a packaging change. The new name of the system is the Renovis S141 Lumbar Interbody Fusion System (S141 System).

The S141 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.

The Ti6Al4V is compliant with ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.

The system also includes instruments which are manufactured from stainless steel in compliance with ASTM A564-13 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes.

E) Intended Use/Indications For Use:

The Renovis S141 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). Renovis S141 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 S141 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

F) Substantial Equivalence Comparison and Discussion

A reference device (K2M Cascadia, K150481) is included.

The modified and new cages have the same Indications for Use, same surgical procedure, a porous structure applied to the superior and inferior surface area, are manufactured from Ti6Al4V in compliance with ASTM F136, and are gamma sterilized, the same as the predicate cages. The new and modified cages are dimensionally equivalent in overall form and fit (sizes and footprint) to the predicate cages, and are within the specifications of the FDA cleared cages.

Internal dimensional specification changes, and change in porous structure were assessed for risk and tested under Design Controls. The manufacturing change was validated.

G) Performance - Bench

The following performance testing was successfully conducted:

- Dynamic Compression
- Stereological, SEM and ECD evaluation
- Mechanical strength of porous structure:
  - Static Tensile testing
  - Static Shear testing

  - Shear Fatigue testing
  - Compressive Elastic Modulus testing
  - Tensile Elastic Modulus testing
  - Abrasion resistance testing
- Cytotoxicity and bacterial endotoxin testing
- Cytotoxicity
- Pyrogenicity testing

H) Compliance with Standards or FDA Guidance

The Renovis S141 System cages comply with the following:

- ASTM E8/E8M-15 Standard Test Methods for Tension Testing of Metallic Materials
- ASTM E9-09 Standard Test Methods of Compression Testing of Metallic Materials at Room Temperature
- ASTM F1044-05 (R)2011 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147-05 (R)2011 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings
- ASTM F1160-14 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 F1978-12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F2077-14 Test methods for intervertebral body fusion devices
- ASTM F2847-10:2010 Standard Practice for Reporting and Assessment of Residues on Single Use Implants
- AAMI/ANSI ST72:2011 (R)2016 Bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing
- AAMI/ANSI/ISO 10993-1:2009 (R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- 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 changes described for the modified cages or with the new cages. Testing, where applicable, was verified under Design Controls and found to be acceptable.

The modified and new S141 System Ti6Al4V cages are substantially equivalent to the predicate S141 System Ti6Al4V cages.