December 7, 2018

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

Re: K182007
Trade/Device Name: Renovis Tesera C/Tesera SC Anterior Cervical Fusion (ACF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: November 5, 2018
Received: November 7, 2018

Dear Ms. 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)*
K182007

Device Name
Renovis Tesera C/Tesera SC Anterior Cervical Fusion (ACF) System

Indications for Use *(Describe)*
The Renovis Tesera SC Stand-alone ACF System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. Renovis Tesera SC Stand-alone ACF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.
The Renovis Tesera SC Stand-alone ACF System is a stand-alone system when used with the cover plate and screws provided, and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of three (3) screws and the cover plate assembly. When used without the cover plate and three screws the Renovis Tesera SC Stand-alone ACF System is a non-stand-alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

The Renovis Tesera C ACF System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. Renovis Tesera C ACF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.
The Renovis Tesera C ACF System is a non-stand-alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

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)
K182007

A) Submitted by: Renovis Surgical Technologies Inc.
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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

Date prepared: December 7, 2018

B) Device Name: Intervertebral fusion device with integrated fixation, cervical
Intervertebral fusion device with bone graft, cervical

Proprietary Name: Renovis Tesera C/Tesera SC Anterior Cervical Fusion (ACF) System

Device Class: Class II

Regulation number: 21 CFR 888.3080

Regulation name: Intervertebral body fusion device

Product code: OVE - intervertebral fusion device with integrated fixation, cervical
ODP - intervertebral fusion device, cervical

Classification panel: Orthopedic

C) Primary predicate: K153250-Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System

D) Additional Predicate: K181655-Renovis S180 Lateral Lumbar Interbody Fusion System

E) Device Description:

Tesera (or T3) describes Renovis' proprietary Tesera Trabecular Technology™ Porous Structure for the manufacture of the porous titanium on the superior and inferior surfaces of the implant.

RENOVIS

The Renovis Tesera C/Tesera SC Anterior Cervical Fusion (ACF) System is a single, cervical implant System that includes two (2) "subsystems", the:

- Renovis Tesera C Anterior Cervical Fusion (ACF) System
- Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System

The Renovis Tesera C/Tesera SC Anterior Cervical Fusion (ACF) System cages are additively manufactured from Ti-6Al-4V and are available in a variety of sizes (widths, heights, depths, and lordotic angles) to suit the individual pathology and anatomical conditions of the patient.

The Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System includes cages, and existing bone screws (self-drilling and self-tapping options) and anterior cover plate assembly. When used with the cover plate and screws, the Tesera SC ACF System cages require no supplementary fixation systems. The screws protrude through the interbody portion of the device into the adjacent vertebral bodies. The cages have windows in the side for visualization of the bone graft. When used without the cover plate and screws, the Tesera SC ACF cages require supplemental fixation.

The Renovis Tesera C Anterior Cervical Fusion (ACF) System is not stand alone and requires supplemental fixation.

The Renovis Tesera C/Tesera SC ACF System cages comply with ASTM F2924-14 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion.

The system also consists of reusable instrumentation. The instruments comply with ASTM A564/A64M-13e1 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes or ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.

F) Indications For Use:

The Renovis Tesera SC Stand-alone ACF System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. Renovis Tesera SC Stand-alone ACF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The Renovis Tesera SC Stand-alone ACF System is a stand-alone system when used with the cover plate and screws provided, and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of three (3) screws and the cover plate assembly. When used without the cover plate and three screws the Renovis Tesera SC Stand-alone ACF System is a non-stand-alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

The Renovis Tesera C ACF System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. Renovis Tesera C ACF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The Renovis Tesera C ACF System is a non-stand-alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

G) Substantial Equivalence Discussion

The Renovis Tesera C/Tesera SC ACF System has the same Indication for Use, includes the same geometric and lordotic offerings, are provided standalone or non-standalone, are terminally gamma sterilized, and are additively manufactured from biocompatible materials like the predicate devices.

Differences include manufacturing method, new geometric and lordotic options and packaging. These differences do not raise different issues of safety or effectiveness. Risk analysis conducted under Design Control assessed all differences. Successful manufacturing validation was conducted. The T3 porous shell was evaluated and successfully tested per standards. Mechanical testing of the implant/implant assemblies were tested per standards and found to be acceptable.

The Tesera C/Tesera SC ACF System is substantially equivalent to the predicate devices.

H) Performance Testing - Bench

Mechanical testing of the Renovis Tesera C/Tesera SC ACF System was conducted and found to be acceptable for the following:

- Static Compression, Dynamic Compression, Static Shear Compression, Dynamic Shear Compression, Static Torsion and Dynamic Torsion Testing per ASTM F2077.
- Expulsion testing
- Subsidence testing with and without screws per ASTM F2267

Sterilization validation was completed.

Conclusion

The Renovis Tesera C/Tesera SC ACF System has the same Indication for Use as the Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System.

Differences between the Renovis Tesera C/Tesera SC ACF System and the predicate devices were assessed under Design Control by risk analysis and FEA raises no new safety or effectiveness questions when compared to the predicate device. Mechanical testing was conducted and found to be acceptable. The Renovis Tesera C/Tesera SC ACF System is substantially equivalent to the Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) System.

I) Consensus Standards and FDA Guidance

- AAMI/ANSI/ISO 10993-1:2009/(R)2013 Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within a Risk Management Process
- ASTM F2077-14: Test Methods For Intervertebral Body Fusion Devices
- ASTM F1854-15: Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM F1147-05 (R)2017e1 Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1044-05 (R)2017e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic 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 F1978-17 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F2267-01(R)2011 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- 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 11737-1:2006 R(2011) Sterilization of health care products - microbiological methods - part 1: determination of the population of microorganisms on product
- 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
- 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
- ASTM F 983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments

- 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