November 16, 2017

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

Re: K171543
Trade/Device Name: Renovis Surgical Hip Replacement System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: OQG, OQI, LPH, LZO
Dated: October 12, 2017
Received: October 13, 2017

Dear Sharyn 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,

Katherine D. Kavlock -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)*
K171543

Device Name
Renovis Surgical Hip Replacement System

Indications for Use *(Describe)*
The Renovis Surgical Hip Replacement System is indicated for patients suffering from:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

The Renovis A400 Hip System is intended for cementless applications unless used with the Renovis Cemented Hip Stem.
The Renovis Surgical Porous Coated Acetabular Shell System is intended for cementless applications.
The Cemented Hip Stem is intended for cemented applications.
The Renovis Tesera Trabecular Technologies (T3) Acetabular Shell System is intended for cementless applications.
The Bipolar Head is for use in conjunction with Renovis femoral heads and femoral stems.
Bipolar outer heads are not for use with acetabular shells and liners.

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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RENOVIS

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K171543

A) Submitted by: Renovis Surgical Technologies
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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: Prosthesis, Hip Revision System

Proprietary Name: Renovis Surgical Hip Replacement System

Device Class: Class II

Regulations 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

and Product Codes: OQG, OQI, LPH, LZO

Classification panel: Orthopedic

C) Predicate: K112897 Renovis A400 Surgical Hip Joint Replacement Prosthesis (Tapered Lateral Offset Femoral Stems)
K141676 Renovis Surgical Porous Acetabular Cup System
K143647 Renovis Surgical Hip Replacement System

D) Date Prepared: November 13, 2017

E) Device Description:

The subject of this application is Renovis Extended Lateral Offset Femoral Stems which are an expansion of the FDA cleared Renovis Surgical Hip Replacement System. Extended Lateral Offset Femoral Stems are provided in a variety of sizes to fit patient need. This application also includes a new device specific neck trial and X-ray template, and additional implants and instruments.

The Extended Lateral Offset Femoral Stems are manufactured from the same material as other FDA cleared Renovis femoral stems. The instruments are manufactured from the same material as other instruments included in FDA cleared submissions.

Renovis implants and instruments comply with the following material standards:

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM A564-13 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM A276-17 Standard Specification for Stainless Steel Bars and Shapes

E) Intended Use/Indications For Use:

The Renovis Surgical Hip Replacement System is indicated for patients suffering from:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

The Renovis A400 Hip System is intended for cementless applications unless used with the Renovis Cemented Hip Stem.

The Renovis Surgical Porous Coated Acetabular Shell System is intended for cementless applications.

The Cemented Hip Stem is intended for cemented applications.

The Renovis Tesera Trabecular Technologies (T3) Acetabular Shell System is intended for cementless applications.

The Bipolar Head is for use in conjunction with Renovis femoral heads and femoral stems.

Bipolar outer heads are not for use with acetabular shells and liners.

F) Substantial Equivalence Comparison and Discussion

Additional predicate devices include Renovis FDA cleared Tapered Lateral Offset Femoral Stems in K141676 and K143647. The Extended Lateral Offset Femoral Stems are manufactured in a similar way, from the same material; have the same sizes; same sterilization; and same shelf-life as the Tapered Lateral Offset Femoral Stems in FDA cleared K112897, K141676 and K143647.

The difference between the predicate and new femoral stems is the offering of an extended lateral offset. The results of performance testing support that the Extended Lateral Offset Femoral Stems do not raise new issues of safety and effectiveness and are substantially equivalent to the predicate devices.

G) Performance Testing - Bench

Renovis successfully completed the following performance tests:

- ISO 7206-4: 2010 Implants for surgery - Partial and total hip-joint prostheses - Part 4: Determination of endurance properties and performance of stemmed femoral components
- ISO 7206-6: 2013 Implants for surgery - Partial and total hip joint prostheses - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components
- ANSI/AAMI/ISO 11137-1:2006 (R2010) and A1:2013 Sterilization of health care products – Radiation and Sterilization of health care products
- ANSI/AAMI/ISO 11137-2:2013 Radiation - Part 2: Establishing the sterilization dose

Pyrogenicity Testing

Bacterial endotoxin testing was conducted in compliance with ANSI/AAMI ST72:2011(R)2016 Bacterial endotoxins — Test methods, routine monitoring, and alternatives to batch testing, and endotoxin limits are in compliance with ANSI/AAMI ST72:2011(R)2016.

Biocompatibility, sterilization, and shelf life

There is no change in material, sterilization method or shelf-life from the predicate devices.

H) Additional Consensus Standards and Guidance

- 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

- Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; guidance for Industry and FDA" dated April 30, 2002
- Non-clinical Information for Femoral Stem Prostheses" dated September 17, 2007.
- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff," January 2016, updated March 16, 2016

Conclusion

The Renovis Extended Lateral Offset Femoral Stems are substantially equivalent to the FDA cleared Renovis Tapered Lateral Offset Femoral Stems.