DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 2, 2014

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

Re: K141370
Trade/Device Name: Renovis Cemented Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: June 4, 2014
Received: June 5, 2014

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" (21CFR 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 yours,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141370

Device Name
Renovis Cemented Hip Stem

Indications for Use *(Describe)*
The Renovis A400 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 Cemented Hip Stem is intended for cemented applications.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K141370

A) Submitted by:

Renovis Surgical Technologies
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Official Contact: Anthony DeBenedictis
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MEDIcept, Inc.
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Prepared: August 26, 2014

B) Classification Name: Prosthesis, hip, semi-constrained, metal/polymer, cemented

Common Name: Hip joint metal/polymer semi-constrained cemented prosthesis

Proprietary Name: Renovis Cemented Hip Stem

Device Class: Class II

Regulation and Product Code: 21 CFR 888.3350
JDI

Classification panel: Orthopedic

C) Predicate: K970351, K963509 Smith & Nephew Global Taper Spectron Hip Stems (for cemented hip stems)

D) Device Description

The Renovis Cemented Hip Stem is for use with bone cement only, is offered in multiple sizes, and is manufactured from CoCr. The taper connection of the Renovis Cemented Hip Stem is the same as the existing Renovis FDA cleared Renovis uncemented hip stems (K112897) to allow use with the existing FDA cleared femoral heads (CoCr and ceramic femoral heads; K112897 and K131354). A distal plug and distal centralizers are also offered and are manufactured from PMMA.

Materials

- Cemented hip stems comply with ASTM F799-11 Standard Specification for Cobalt-28 Chromium-6Molybdenum Alloy Forgings for Surgical Implants
- Distal centralizer and distal plug comply with ASTM D5436-13 Standard Specification for Cast Poly(Methyl Methacrylate) Plastic Rods, Tubes, and Shapes
- Cemented hip stem specific instruments comply 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 A400 Surgical Hip Replacement System is indicated for patients suffering from:
1. Noninflammatory 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.
5. Revision procedures where other treatment or devices have failed.

The Cemented Hip Stem is intended for use in cemented applications.

F) Substantial Equivalence Comparison

The Renovis Cemented Hip Stem has similar Indications for Use, material, dimensions, operating principle and basic design as the predicate device, and both offer the stems as gamma sterilized. Fatigue testing of worst case Renovis stems was successfully conducted.

H) Performance Testing

Per "Guidance for Industry and FDA Staff – Non-clinical Information for Femoral Stem Prostheses, September 2007, the following performance testing was successfully conducted:

- Femoral stem fatigue per 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
- Femoral neck fatigue, as compared to standards criteria per ISO 7206-6: 1992 Implants for surgery - Partial and total hip joint prostheses - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components

I) Compliance with Other Standards

- ASTM F983-86 (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
- ISO 11137-2:2013 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose

- ISO 11607-2: 2009 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes; Operational Qualification Section 5.3 and Performance Qualification Section 5.4
- ASTM F1980-07 (reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 2A Partial Simulation Performance Tests; Packaged-Products weighing 150 lb (68 kg) or Less
- ANSI/AAMI/ISO 11135-1:2007- Part 1, Sterilization of healthcare products-Ethylene Oxide-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals, for limited exposure device type.

Conclusion

The Renovis Cemented Hip Stem does not raise new issues of safety or effectiveness and is substantially equivalent to the predicate device.