Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K131354

A) Submitted by: Renovis Surgical Technologies
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SEP 19 2013

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Prepared: August 13, 2013

B) Classification Name: Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

Common Name: Bipolar Hip System

Proprietary Name: Renovis Bipolar Hip System

Device Class: Class II

Regulation and Product Code: 21 CFR 888.3390
KWY

Classification panel: Orthopedic

C) Predicates: Aesculap Bipolar Acetabular Cup, K060707, KWY
StelKast Bipolar Hip System, K 972961, KWY, JDI

D) Device Description:

The Renovis Bipolar Hip System includes a bipolar head and 22 mm femoral heads. The Renovis Bipolar heads are offered in a range of inner and outer dimensions from 39 to 65 mm to fit either 22 or 28 mm femoral heads. Renovis already has FDA clearance for a 28 mm femoral head (K112897).

The bipolar head is a sub-component of a hip replacement construct where it assumes the function of the natural femoral head and is combined with a femoral head and hip stem. It consists of a highly polished CoCr alloy outer shell and a polyethylene insert. The ultra-high-molecular weight polyethylene (UHMWPE) insert is comprised of an inner liner and a locking ring. The bipolar head has two articulation surfaces: the outer CoCr head articulates with the patient's natural acetabular cartilage and the inner UHMWPE liner articulates with the femoral head assembled to the femoral stem. The modular CoCr alloy femoral head, is held in place within the bipolar head by a retaining ring that is pre-assembled into the polyethylene insert.

The bipolar heads and femoral heads are gamma sterilized. The system is offered with the full instrumentation required for the procedure.

E) Intended Use/Indications For Use:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other technique

F) Substantial Equivalence Comparison and Discussion

The Renovis Bipolar Hip System application includes a bipolar head (cup) and 22 femoral head. The Bipolar Hip System:

- Is the same technology (material and design) as the predicate devices
- Has the same or similar Indications for Use as the predicate device
- Has the same bipolar head inner and outer dimensional sizes as the predicate devices
- Uses a slightly different size femoral head than one of the predicate devices, but the same as the other predicate device

Discussion

The Renovis Bipolar Hip System is substantially equivalent to the predicate devices, and any slight differences do not raise new issues of safety or effectiveness.

G) Performance Testing

The Renovis Bipolar Hip System has successfully undergone ASTM performance testing in compliance with ASTM F1820-13 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices, but with deviations specific for testing of a bipolar head.

H) Compliance with Standards

The Renovis Bipolar Hip System complies with the following Standards:

- ISO 5832-4:1996 Metallic materials -- Part 4: Cobalt-chromium-molybdenum casting alloy
- ISO 5834-2:2011 Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms
- ASTM F1537-8 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
- ASTM F983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F2033-12 Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials
- ASTM F1820-13 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices with deviations
- ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ISO 17665-1:2006 Sterilization of health care products – Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Conclusion

The results of the Renovis Bipolar Hip System performance testing indicate that the device performs as expected. The Renovis Bipolar Hip System has the same Intended Use/Indications for use as the predicate devices, and any slight differences from the predicate devices do not raise new or different issues of safety or effectiveness. Therefore, the Renovis Bipolar Hip System is substantially equivalent to the predicate devices.

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

September 19, 2013

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

Re: K131354
Trade/Device Name: Renovis Bipolar Hip System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: August 14, 2013
Received: August 19, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131354

Device Name: Renovis Bipolar Hip System

Indications for Use:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other technique

Prescription Use____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S