Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K132312

A) Submitted by: Renovis Surgical Technologies Inc.
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Ashland, MA 01721

Date prepared: April 2, 2014

B) Device Name: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

Common Name: Total Hip Arthroplasty – Acetabular Components

Proprietary Name: Renovis Tesera Trabecular Technology (T^3) Acetabular Shell System

Device Class: Class II

Regulation number: 21 CFR 888.3358

Regulation name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Product code: LPH

Classification panel: Orthopedic

C) Predicates:

K112897	Renovis A400 Surgical Hip Replacement System (acetabular shells)
K102975	Exactech Novation Crown Cup with InteGrip Acetabular Shell

D) Device Description:

The Renovis Tesera Trabecular Technology (T^3) Acetabular Shell System ("T^3 Acetabular Shell System") acetabular shells ("T^3 shells") are modifications of the Renovis A400 Surgical Hip Replacement System acetabular shells cleared through premarket notification K112897. This submission proposes the following design change: The proposed T^3 shells will be manufactured from the same titanium alloy using an additive manufacturing process to fabricate the implant and porous structure concurrently, and have a thicker solid substrate and porous layer.

The T^3 shells are to be used with polyethylene liners, femoral components, acetabular shell trials, and other system specific instruments originally cleared in the Renovis A400 Surgical Hip System (K112897). The T^3 shell is available in multiple configurations (no hole shell; cluster hole shell) and sizes (44 – 66 mm diameter). The liners attach to the shells under impaction with a snap lock mechanism.

The T^3 shells comply with the following material standards:

- ASTM F136-12(a) Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F3001-13 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion

E) Indications For Use:

The Renovis Tesera Trabecular Technology (T^3) Acetabular Shell System components are to be used with components of the Renovis A400 Surgical Hip Replacement System, and are indicated for patients suffering from the following:

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 Tesera Trabecular Technology (T^3) Acetabular Shell System is intended for cementless applications.

F) Substantial Equivalence Comparison and Discussion

The T^3 Acetabular Shell System has similar Indications for Use, design, material, sizes and geometries, and compatible liners and femoral components as the K112897 A400 acetabular shells. The T^3 Acetabular Shell System additive manufacturing process is similar to that of the K102975 Exactech acetabular shells. The T^3 shells have a thicker porous structure and solid substrate than the K112897 A400 acetabular shells. Differences between the Renovis T^3 shells and the predicate devices do not raise any new issues of safety or effectiveness.

G) Biocompatibility

The biocompatibility of Ti-6Al-4V EBM manufactured FDA cleared orthopedic implants has been demonstrated.

H) Performance Testing - Bench

The following performance tests were successfully conducted:

- ASTM F1044-05 (2011) Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1160-05 (2011) Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium/Phosphate Metallic Coatings
- ASTM F1147-05 (2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1854-09 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
  The results of ASTM F1854 testing demonstrate compliance with the requirements in 21 CFR 888.3358 for volume porosity, average pore size, and interconnecting porosity and porous coating thickness
- ASTM F1978-12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- Acetabular shell fatigue testing compared to a predicate device per Renovis protocol and ASTM F1820-97 Standard Test Methods for Determining the Axial Disassembly Force of a Modular Acetabular Device

Sterilization and aging validation studies were conducted previously.

Conclusion

The similarity in Indications for Use, sizes, geometries and technology and the performance testing and biocompatibility data submitted support that the Renovis T^3 Acetabular Shell 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

April 11, 2014

Renovis Surgical Technologies Incorporated
% Dr. Sharyn Orton
Senior Consultant
MEDIcept, Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K132312
Trade/Device Name: Renovis Tesera Trabecular Technology (T^3) Acetabular Shell 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: LPH
Dated: March 12, 2014
Received: March 13, 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 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" (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 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,

Lori A. Wiggins

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): K132312

Device Name: Renovis Tesera Trabecular Technologies (T^3) Acetabular Shell System

Indications for Use:

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The Renovis Tesera Trabecular Technologies (T^3) Acetabular Shell System is intended for cementless applications.

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 D. Frank -S

Division of Orthopedic Devices