June 20, 2019

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

Re: K190122
Trade/Device Name: Renovis A200 PS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: May 16, 2019
Received: May 20, 2019

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
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)*
K190122

Device Name
Renovis A200 PS Knee System

Indications for Use *(Describe)*
The A200 Knee System is intended for use in total knee arthroplasty for the following indications:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is for cemented use only.

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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Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K190122

A) Submitted by: Renovis Surgical Technologies Inc.
1901 W. Lugonia Ave, Ste 340
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

Date prepared: 5/16/2019

B) Device Name: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer;
Prosthesis, knee, patellofemorotibial. semi-constrained, cemented, polymer + additive/metal/polymer +

Proprietary Name: Renovis A200 PS Knee System

Device Class: Class II

Regulation number: 21 CFR 888.3650

Product codes: JWH, OIY

Classification panel: Orthopedic

C) Predicate: Primary: K120038 Renovis A200 Knee System
K113550 Biomet Vanguard Complete Knee System

D) Device Description:

The Renovis A200 PS Knee System is a patellofemorotibial polymer/metal/polymer semiconstrained prosthesis intended to be implanted to replace a knee joint. The system consists of femoral, tibial and patella components intended for use with bone cement.

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The subject of this 510k Premarket Notification are additional offerings to the Renovis A200 Knee System (K120038) resulting from customer requests to better meet patient need (anatomy and surgical technique). The additional offerings are part of the FDA cleared A200 Knee System and are called the A200 PS Knee System. The PS Knee System is a primary, posterior stabilized (PS), tri-compartmental knee replacement system to treat knee disorders resulting from degenerative diseases where the posterior cruciate ligament is absent.

The new A200 PS Knee System includes:

- Femoral components in nine (9) sizes (1, 2, 3, 3N, 4, 4N, 5, 6, and 7) in a posterior stabilized (PS) design, each for left and right sides, manufactured from CoCrMo in compliance with ASTM F75-18 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants
- Tibial insert components in three (3) footprint sizes; each for the left and right sides; with articulating thicknesses ranging from 10 mm to 23 mm; in two levels of constraint - PS and PS Plus. The tibial inserts have a mechanical lock to the tray (snap mechanism). Tibial inserts are manufactured from highly cross-linked UHMWPE (with and without 0.1% by wt Vit E), and 1020 UHMWPE in compliance with ASTM F648-14 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants and ASTM F2695 -12 Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
- Patellar components in five (5) sizes in sombrero and five (5) sizes in domed design. Patellar components are manufactured from highly cross-linked UHMWPE (with and without 0.1% by wt Vit E), and 1020 UHMWPE in compliance with ASTM F648-14 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants and ASTM F2695 -12 Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
- FDA cleared (K120038) Tibial tray (baseplate) components in (9) sizes, each for the left and right sides, and in each in two designs, a conical design (CoCrMo) and a keeled design (Ti6Al4V)

The system also includes reusable instrumentation. The instruments are manufactured from medical grade Polyphenylsulfone (PPSU) and silicone, as well as Medical-Grade Stainless Steel (SS), in compliance with:

- 17-4 SS per ASTM A564-2010
- 420 SS per ASTM F899-2012
- 455 SS per ASTM A564-2010
- 465 SS per ASTM A564-2010
- 301 SS per ASTM A276-2017 or F899-2012
- 302 SS per ASTM A276-2017 or F899-2012
- 304 per ASTM A240-2017, A276-2017, or F899-2012
- 316 SS per ASTM A240-2017, A276-2017, or F899-2012
- Nitronic 60 SS per ASTM F899-2012

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E) Indications For Use:

There is no change in the Indications for Use as the A200 PS Knee System is part of the A200 Knee System.

The A200 Knee System is intended for use in total knee arthroplasty for the following indications:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure

This device is for cemented use only.

F) Substantial Equivalence Discussion

Compared to the predicate devices, the Renovis A200 PS Knee System has the same Indications for Use.

Compared to the primary predicate Renovis A200 Knee System (K120038), the Renovis A200 PS Knee System:

- Has the same:
  - Materials:
    - Femoral components from CoCrMo in compliance with ASTM F75-18 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants
  - Tibial inserts and patella components from highly cross-linked UHMWPE with and without 0.1% by wt Vit E) in compliance with ASTM F648-14 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants and ASTM F2695-12 Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
  - Tibial trays (from K120038)
  - Sombrero patella design and dimensions
  - Locking mechanism (from K120038)
  - Gamma or EO Sterilization
- Similar tibial insert sizes and dimensions
- Additionally offers:
  - Posterior stabilized design
  - Tibial inserts and patella components manufactured from UHMWPE 1020 in compliance with ASTM F648-14 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
  - A Tibial Insert with a 23 mm articulating thickness
  - Domed patella component, but with the same dimensions and number of pegs as the sombrero patella component

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Similar to the predicate Biomet Vanguard Complete Knee System (K113550, PS design), the Renovis A200 Knee System offers:

- Posterior stabilized design
- Domed, three peg patella

Testing of the Renovis A200 PS Knee System was conducted (and compared to data from contemporary PS designs or the literature, where applicable). The results for all testing were found to be acceptable for the system design.

G) Performance Testing - Bench

Testing of the Renovis A200 PS Knee System components was conducted and found to be acceptable for the following:

- Tibial Post Fatigue Strength (static and fatigue)
- Tibial Tray Locking Mechanisms Testing
- Tibial-Femoral Constraint Testing
- Tibial-Femoral Contact Area/Contact Stress Testing
- Patello-Femoral Lateral Subluxation and Contact Area/Contact Stress Testing

Conclusion

It has been demonstrated that A200 PS Knee System testing is consistent with the performance testing of other knee systems, and will perform as expected. The Renovis A200 PS Knee System has the same Indications for Use as the predicate devices. Differences between Renovis A200 PS Knee System and predicate devices do not raise or cause different issues of safety or effectiveness. The Renovis A200 PS Knee System is substantially equivalent to the predicate devices.

H) Consensus Standards

The Renovis A200 PS Knee complies with the following additional standards:

- ISO 7207-2:2011 Implants For Surgery - Components For Partial And Total Knee Joint Prostheses - Part 2: Articulating Surfaces Made Of Metal, Ceramic And Plastics Materials [Including AMENDMENT 2 (2016)]
- ASTM F2083:2012 Standard Specification for Knee Replacement Prosthesis
- ANSI/AAMI ST72:2011 (R2016) Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
- BS EN ISO 11137-2:2015 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
- AAMI/ANSI/ISO 10993-7:2008(R)2012, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

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- ANSI/AAMI/ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices
- ISO 11607-1:2006/Amd 1:2014 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 11607-2:2006/Amd 1:2014 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming sealing and assembly processes.
- ASTM F88-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)