October 22, 2019

Implanet, S.A.
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K192084
Trade/Device Name: Madison Total 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
Dated: August 2, 2019
Received: August 2, 2019

Dear Hollace Rhodes:

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 Ting Song
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
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)*

K192084

Device Name
Madison Total Knee System

Indications for Use *(Describe)*

The Madison Knee System is intended for total knee replacement. Madison Knee components are for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as: painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis; and revision of previous unsuccessful knee replacement or other procedure. These components are indicated for cemented fixation 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Device Trade Name: Madison Total Knee System

Common Name: Total Knee Prosthesis

Manufacturer:
Implanet, S.A.
Technopole Bordeaux Montesquieu
Allée Francois Magendie
33650 Martillac
France
Phone: (+33) 557 995 555
Facsimile: (+33) 557 995 700

Contact:
Régis Le Couëdic
Regulatory Affairs & Quality Director
Phone: +33 685 22 26 55
Email: rlc@implanet.com

Prepared by:
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
Phone: (202) 552-5800

Date Prepared: October 1, 2019

Classification: 21 CFR 888.3560

Class: II

Product Code: JWH

Indications for Use:

The Madison Knee System is intended for total knee replacement. Madison Knee components are for use in total knee arthroplasty to relieve pain and restore knee functions for indications such as: painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis; and revision of previous unsuccessful knee replacement or other procedure. These components are indicated for cemented fixation only.

Device Description:

The Madison Total Knee System is a modular knee system consisting of a femoral component, tibial insert, tibial baseplate, tibial stem extensions, and a patella. The system components are designed to be Cruciate-Retaining and Ultra-Congruent. The femoral component and tibial baseplate are manufactured from Cobalt Chrome and are to be implanted with cement. The tibial stem extensions are manufactured from titanium alloy, and the tibial insert and patella components are manufactured from UHMWPE. All implant components are provided sterile.

Predicate Device:

The Scorpio NRG Knee System (K915192, K071991) serves as the predicate device.

Technological Characteristics Comparison:

The Madison Total Knee System and its predicate device are similar in size, material, and geometry. Both the subject and predicate devices are fixed, cruciate-retaining, and are to be used with bone cement. Both systems are semi-constrained and utilize a metal-on-polyethylene articulation. There are no substantial differences in technological characteristics between the two devices and as such the Madison Total Knee System introduces no new issues of safety or effectiveness.

Nonclinical Testing:

All necessary testing has been performed for the worst-case Madison Total Knee System components to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Clinical data were not needed to support the safety and effectiveness of the subject device.

The device performance was characterized through the following tests:

- Range of Motion (Tibiofemoral) as per ASTM F2083
- Constraint (Tibiofemoral) as per ASTM F1223
- Contact Area/Contact Stress (Tibiofemoral)
- Component Interlock Strength
- Range of Motion/Constraint (Patellofemoral) as per ASTM F1223
- Contact Area/Contact Stress (Patellofemoral)
- Tibial Baseplate Cantilever Fatigue as per ASTM F1800
- UHMWPE Characterization as per ASTM F648
- Bacterial Endotoxin Testing

Conclusion:

The Madison Total Knee is substantially equivalent to the predicate device with respect to its indications for use, design, function, and method of fixation.