March 11. 2020

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

Re: K200328
Trade/Device Name: Tesera Trabecular Technologies (T3) Acetabular Shell System, Porous Acetabular Cup 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: OQG, LPH, LZO, OQI
Dated: February 6, 2020
Received: February 10, 2020

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,

Vesa Vuniqi, MS
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)*
K200328

Device Name
Kyocera Medical Technologies, Inc. ("KMTI") Hip Replacement System

Indications for Use *(Describe)*
The KMTI 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.

Qualifiers:
The KMTI A400 Hip System is intended for cementless applications unless used with the KMTI Cemented Hip Stem.

The KMTI Porous Coated Acetabular Shell System is intended for cementless applications. In addition, the KMTI Porous Coated Acetabular Shell and Universal liners can be used with the Kyocera Corporation ("KYOCERA") Initia Total Hip System femoral stem mated with KYOCERA CoCr (28-40mm) or BIOCERAM AZUL (28-40mm) femoral head.

The Cemented Hip Stem is intended for cemented applications.

The KMTI Tesera Trabecular Technology (T3) Acetabular Shell System is intended for cementless applications. In addition, the KMTI T3 Acetabular Shell and Universal liners can be used with the KYOCERA Initia femoral stem mated with KYOCERA CoCr (28–40mm) or BIOCERAM AZUL (28-40mm) femoral head.

The Bipolar Head is for use in conjunction with KMTI femoral heads and femoral stems.
Bipolar outer heads are not for use with acetabular shells and liners.

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."

Special 510(k) Premarket Notification Summary
as required by 21 CFR 807.92(a)

A) Submitted by: Kyocera Medical Technologies, Inc.
1200 California St. Suite 210
Redlands, CA 92374
Phone: 909-557-2360
Fax: 909-839-6269

Official Contact: Anthony DeBenedictis
Divisional Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721

B) Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Proprietary Name: Kyocera Medical Technologies, Inc. ("KMTI") Hip Replacement System which includes:
- KMTI Tesera Trabecular Technologies (T3) Acetabular Shell System
- KMTI Porous Acetabular Cup System

Device Class: Class II

Regulation: 21 CFR 888.3358

Product Code: OQG, LPH, LZO, OQI

Classification panel: Orthopedic

C) Predicates: Primary: K132312 Renovis Tesera Trabecular Technologies (T3) Acetabular Shell System
Secondary: K141676 Renovis Porous Acetabular Cup System

D) Date Prepared: February 6, 2020

E) Device Description:

The Renovis Surgical Hip Joint Replacement System (K112897) includes multiple subsystem offerings, including:

- K132312: Renovis Tesera Trabecular Technologies (T3) Acetabular Shell System
- K141676: Renovis Porous Acetabular Cup System

Renovis Surgical Technologies is now wholly owned by Kyocera International, Inc. (San Diego, CA) as Kyocera Medical Technologies, Inc. ("KMTI"). The subject of this Special 510k Premarket Notification are additional KMTI offerings which include the use of components of the K160895 Kyocera Medical Corporation, Japan Initia Total Hip System (now Kyocera Corporation, Japan; "KCJ") that may be used with the KMTI K132312 T3 acetabular shell, K141676 porous acetabular shell and KMTI universal acetabular liners.

F) Intended Use/Indications For Use:

The KMTI 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.

Qualifiers:
The KMTI A400 Hip System is intended for cementless applications unless used with the KMTI Cemented Hip Stem.

The KMTI Porous Coated Acetabular Shell System is intended for cementless applications. In addition, the KMTI Porous Coated Acetabular Shell and Universal liners can be used with the Kyocera Corporation ("KYOCERA") Initia Total Hip System femoral stem mated with KYOCERA CoCr (28-40mm) or BIOCERAM AZUL (28-40mm) femoral head.
The Cemented Hip Stem is intended for cemented applications.

The KMTI Tesera Trabecular Technology (T3) Acetabular Shell System is intended for cementless applications. In addition, the KMTI T3 Acetabular Shell and Universal liners can be used with the KYOCERA Initia femoral stem mated with KYOCERA CoCr (28–40mm) or BIOCERAM AZUL (28-40mm) femoral head.

The Bipolar Head is for use in conjunction with KMTI femoral heads and femoral stems. Bipolar outer heads are not for use with acetabular shells and liners.

G) Substantial Equivalence Comparison and Discussion

There is no change in the Intended Use/Indications for Use; no change in implant materials, manufacturing, packaging, and/or sterilization. Equivalence of KCJ components to KMTI components has been demonstrated.

H) Compliance with Design Controls

All changes were assessed for risk and successfully evaluated under Design Controls. Range of Motion analysis was successfully conducted.

I) Compliance with Standards or FDA Guidance

- ISO 21535:2007/Amd 1: 2016 Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants — Amendment 1
- ASTM F1820-13 Standard Test Methods for Determining the Forces for Disassembly of Modular Acetabular Devices

Conclusion

The KCJ CoCr or BIOCERAM AZUL femoral head/Initia femoral stem with the KMTI universal liner and T3 acetabular shell or Porous acetabular shell is substantially equivalent and expected to have equivalent performance to the KMTI CoCr or Biolox delta ceramic femoral head/femoral stem with the KMTI universal liner and T3 acetabular shell or Porous acetabular shell.