



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

Re: K203472

Trade/Device Name: KMTI Hip Replacement 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: March 29, 2021

Received: March 31, 2021

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Vesa Vuniqui  
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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2023  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)  
K203472

Device Name  
KMTI Hip Replacement System

### Indications for Use (Describe)

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 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 BIO CERAM AZUL (28-40mm) femoral head.
- The KMTI femoral stem mated with KYOCERA CoCr (28-40mm) or BIO CERAM AZUL (28-40mm) femoral head.
- The KYOCERA Initia femoral stem mated with KMTI CoCr (28-40mm) or BIOLOX® delta (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 BIO CERAM AZUL (28-40mm) femoral head.
- The KMTI femoral stem mated with KYOCERA CoCr (28–40mm) or BIO CERAM AZUL (28-40mm) femoral head.
- The KYOCERA Initia femoral stem mated with KMTI CoCr (28-40mm) or BIOLOX® delta (28-40mm) femoral head.

The Bipolar Head is for use in conjunction with KMTI femoral heads and femoral stems.

In addition:

- The KYOCERA 28mm CoCr and 28mm BIO CERAM AZUL femoral heads and Initia femoral stem can be used with the KMTI 28mm ID Bipolar Head.
- The KYOCERA Initia femoral stem can be used with the KMTI 22mm CoCr femoral head and KMTI 22mm ID Bipolar Head.

The Bipolar Head is for uncemented use only.

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.**



**Special 510(k) Premarket Notification Summary  
as required by 21 CFR 807.92(a)  
K203472**

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  
Reference device: K200709 Kyocera Bipolar Hip System

D) Date Prepared: 3/31/2021

## E) Device Description:

The Kyocera Medical Technologies, Inc. (“KMTI”) Hip Replacement System 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 known as Kyocera Corporation) that may be used with the KMTI K132312 T3 acetabular shell, K141676 porous acetabular shell and KMTI Universal Liners.

## F) Intended Use/Indications For Use:

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 KMTI femoral stem mated with KYOCERA CoCr (28-40mm) or BIOCERAM AZUL (28-40mm) femoral head.
- The KYOCERA Initia femoral stem mated with KMTI CoCr (28-40mm) or BIOLOX® delta (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 KMTI femoral stem mated with KYOCERA CoCr (28–40mm) or BIOCERAM AZUL (28-40mm) femoral head.
- The KYOCERA Initia femoral stem mated with KMTI CoCr (28-40mm) or BIOLOX® delta (28-40mm) femoral head.

The Bipolar Head is for use in conjunction with KMTI femoral heads and femoral stems. In addition:

- The KYOCERA 28mm CoCr and 28mm BIOCERAM AZUL femoral heads and Initia femoral stem can be used with the KMTI 28mm ID Bipolar Head.
- The KYOCERA Initia femoral stem can be used with the KMTI 22mm CoCr femoral head and KMTI 22mm ID Bipolar Head.

The Bipolar Head is for uncemented use only.

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. Fret corrosion risk was assessed by comparison to K200709 Kyocera Bipolar Hip System (reference device), femoral head and femoral stem design attribute data analysis and rationale, and literature references. Equivalence of the use of KYOCERA components and use of KMTI components has been demonstrated.

#### H) Compliance with Design Controls

All changes were assessed for risk and successfully evaluated under Design Controls. The following were successfully conducted:

- Static compression burst test
- Post-fatigue static compression burst test
- Oblique (off-axis) fatigue test
- Pull-off tests
- Static torsion tests
- Stem fatigue test
- Head neck fatigue test
- ROM analysis
- Impingement analysis

## I) Compliance with Standards or FDA Guidance

- ISO 7206-4:2010/AMD 1:2016 *Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components — Amendment 1*
- ISO 7206-6:2013 *Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components*
- ISO 7206-10:2018 *Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*
- ISO 7206-13: 2016 *Implants for surgery - Partial and total hip joint prostheses - Part 13: Determination of resistance to torque of head fixation of stemmed femoral components*
- ASTM F2009 (2011) *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Protheses*
- ASTM F2345-03(2013) *Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads*
- *Guidance Document For The Preparation Of Premarket Notification For Ceramic Ball Hip Systems, Draft, January 10, 1995*

*Conclusion*

The performance of the KMTI BIOLOX delta and CoCr femoral heads mated with the KYOCERA Initia femoral stem and used with the KMTI T3 acetabular shell or Porous acetabular shell and Universal Liner is substantially equivalent to and expected to have equivalent performance to the KMTI femoral head/femoral stem used with the KMTI T3 acetabular shell and Porous acetabular cup and Universal Liner.