



April 4, 2024

Kyocera Medical Technologies, Inc.  
% Nathan Wright  
Engineer & Regulatory Specialist  
Empirical Technologies  
4628 Northpark Drive  
Colorado Springs, CO 80918

Re: K232114

Trade/Device Name: TRIBRID® Unicompartmental Knee System  
Regulation Number: 21 CFR 888.3520  
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis  
Regulatory Class: Class II  
Product Code: HSX  
Dated: March 7, 2024  
Received: March 8, 2024

Dear Nathan Wright:

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 (the 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 available 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](#).

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G.  
Allen -S  
Date: 2024.04.04 16:21:20  
-04'00'

For: Lixin Liu, PhD  
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

## Indications for Use

510(k) Number (if known)

K232114

Device Name

TRIBRID® Unicompartmental Knee System

Indications for Use (Describe)

The Kyocera TRIBRID® Unicompartmental Knee System is indicated for use in patients with the following:

- Painful and disabled knee joint resulting from osteoarthritis, traumatic arthritis, or idiopathic osteonecrosis, of either the medial or lateral compartments.
- Correction of varus, valgus, or posttraumatic deformity.
- As an alternative to tibial osteotomy in patients with unicompartmental NIDJD disease.
- Revision procedures where other treatments or devices have failed.

This device is intended 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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## K232114 - 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1200 California Street Suite 210 Redlands, California 92374
Submitter's Telephone:	(979) 492-6848
Contact Person:	Nathan Wright MS, RAC Empirical Technologies 1-719-351-0248 <a href="mailto:nwright@empiricaltech.com">nwright@empiricaltech.com</a>
Date Summary was Prepared:	April 2, 2024
Trade or Proprietary Name:	TRIBRID® Unicompartmental Knee System
Device Classification Name:	Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer
Classification & Regulation #:	Class II per 21 CFR §888.3520
Product Code:	HSX
Classification Panel:	Orthopedic



### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

KMTI's TRIBRID® Unicompartmental Knee System is a partial knee replacement prostheses intended for application with bone cement. Partial knee replacement components include femoral and tibial components. Femoral baseplates are CoCrMo Alloy while the Tibial implants are Ti6Al4V Alloy. The Tibial bearing inserts are made from Ultra-High Molecular Weight Polyethylene (UHMWPE) variations. Components are available in a variety of designs and size ranges intended for both primary and revision applications.

### INDICATIONS FOR USE

The Kyocera TRIBRID® Unicompartmental Knee System is indicated for use in patients with the following:

- Painful and disabled knee joint resulting from osteoarthritis, traumatic arthritis, or idiopathic osteonecrosis, of either the medial or lateral compartments.
- Correction of varus, valgus, or posttraumatic deformity.
- As an alternative to tibial osteotomy in patients with unicompartmental NIDJD disease.
- Revision procedures where other treatments or devices have failed.

This device is intended for cemented use only.

### TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

**Predicate Devices**

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Product Code</b>	<b>Type</b>
K190085	JOUNEY II Unicompartmental Knee	Smith & Nephew, Inc.	HSX	Predicate
K183029	MOTO™ Lateral Partial Knee System	Medacta International SA	HSX	Reference Device
K190122	Renovis A200 PS Knee System	Revnovis (now Kyocera Medical Technologies, Inc.)	JWH, OIY	Reference Device

**PERFORMANCE DATA**

The TRIBRID® Unicompartmental Knee System has been tested in the following test modes:

- Baseplate Fatigue Testing per ASTM F3140-17
- Intrinsic Stability Characteristics
- Modular Disassembly Characteristics per ASTM F1814 and ASTM F2083
- Femoral Component Durability Testing per ASTM F3210-22
- Range of Motion Assessment per ASTM F2083
- Simulated Wear per ISO 14243-3

The results of this non-clinical testing show that the strength of the TRIBRID® Unicompartmental Knee System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

**CONCLUSION**

The overall technology characteristics and mechanical performance data lead to the conclusion that the TRIBRID® Unicompartmental Knee System is substantially equivalent to the predicate device.