April 10, 2025

Kyocera Medical Technologies, Inc.
% Hannah Taggart
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K242045
Trade/Device Name: Initia T3 Acetabular Hemispherical Shell 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: LPH, LZO
Dated: March 3, 2025
Received: March 3, 2025

Dear Hannah Taggart:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242045

Device Name
Initia T3 Acetabular Hemispherical Shell 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.

The Initia T3 Acetabular Hemispherical Shell System is intended for cementless applications.

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.

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K242045 510(K) SUMMARY

Submitter's Name:	Kyocera Medical Technologies, Inc.
Submitter's Address:	1200 California Street Suit 210 Redlands, CA 92374
Submitter's Telephone:	909-557-2360
Contact Person:	Hannah Taggart, MS Empirical Technologies 719-457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	April 3, 2025
Trade or Proprietary Name:	Initia T3 Acetabular Hemispherical Shell System
Device Classification Name:	Prothesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Classification & Regulation #:	Class II per 21 CFR §888.3358
Product Code:	LPH, LZO
Classification Panel:	Joint Arthroplasty Devices (DHT6A)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kyocera Medical Technologies, Inc. (KMTI) Initia T3 Acetabular Hemispherical Shell System is a cementless shell intended for use in the treatment of hip disorders requiring hip replacement surgery. The Initia T3 Acetabular Hemispherical Shell System includes several components including: Initia T3 Acetabular Hemispherical Shell, Initia Acetabular Liner, Initia Bone Screw, and Delta 22.2 Femoral Head.

The Initia T3 Acetabular Hemispherical Shell is a cementless porous shell manufactured from Ti-6Al-4V ELI per ASTM F136. The Initia Acetabular Liner attaches to the inner surface of the Initia T3 Acetabular Hemispherical Shell and is available in four different configurations. The Initia Acetabular Liner is used to provide a single articulation implant option and is manufactured from Vitamin E infused UHMWPE per ASTM F2695 or UHMWPE per ASTM F648. The femoral head is manufactured from Biolox® delta and is available in two offsets.

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.

The Initia T3 Acetabular Hemispherical Shell System is intended for cementless applications.

TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. 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
- Principle of Operation
- Materials of manufacture
- Structural support mechanism
- Range of Sizes

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K160895	Initia Total Hip System & BIOCERAM AZUL® HEAD	KYOCERA	LZO, LPH	Primary
K132312	Tesera Trabecular Technology (T^3) Acetabular Shell System	Renovis Surgical Technologies, Inc.*	LPH	Additional

**Renovis Surgical Technologies, Inc. was purchased by Kyocera Medical Technologies, Inc. in 2019.*

PERFORMANCE DATA

The Initia T3 Acetabular Hemispherical Shell System has been tested in the following test modes:

- Static Testing of Shell Rim and Liner per ISO 7206-12:2016
- Shell Fatigue Testing per ASTM F3090-20
- Shell-Liner Disassembly Testing per ASTM F1820-13
- Dynamic Impingement Testing per ASTM F2582-20 with Post-Impingement Loading
- Range of Motion Testing per ISO 21535:2007
- Pull-off characteristics of Femoral Head per ISO 7206-10
- Ceramic Head Burst Strength, Fatigue, Post-Fatigue Burst Strength, Pull-Off, and Torque-Off
- Particulate Analysis per ASTM F1877
- Characterization of the Porous Surface

The results of this non-clinical testing show that the strength of the Initia T3 Acetabular Hemispherical Shell 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 Initia T3 Acetabular Hemispherical Shell System is substantially equivalent to the predicate device.