January 13, 2024

Kyocera Medical Technologies, Inc.
% Audrey Swearingen
Regulatory Consultant
Swearingen Regulatory Consulting, LLC
16856 Circle Hill Drive
Dexter, Missouri 63841

Re: K243295
Trade/Device Name: Initia 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, OIY
Dated: October 18, 2024
Received: October 18, 2024

Dear Audrey Swearingen:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.01.13 09:50:47 -05'00'

For Lixin Liu, 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.

Submission Number *(if known)*

K243295

Device Name

Initia Knee System

Indications for Use *(Describe)*

The Initia Knee System is intended for use in total knee arthroplasty for the following indications:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is 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.

510(k) Summary

Initia Knee System

1. Submission Sponsor

Kyocera Medical Technologies, Inc. ('KMTI')
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2. Submission Correspondent

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Email: audrey@swearingenregconsulting.com

3. Date Prepared

October 18, 2024

4. Device Identification

Trade/Proprietary Name:	Initia Knee System
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number:	888.3560
Product Codes:	JWH, OIY
Class:	II
Classification Panel:	Orthopedic

5. Legally Marketed Predicate Device

Device name:	A200 Knee System
510(k) number:	K120038, K190122
Manufacturer:	Kyocera Medical Technologies, Inc.; previously Renovis Surgical Technologies LLC

Like the KMTI Initia Knee System, the A200 Knee System predicate device is a patellofemorotibial polymer/ metal/polymer semi-constrained prosthesis to replace a knee joint. The system consists of femoral, tibial and patella components intended for use with bone cement and includes both posterior-stabilizing (PS) and cruciate-retaining (CR) designs.

6. Indication for Use Statement

The Initia Knee System is intended for use in total knee arthroplasty for the following indications:

1. Painful and disabled knee joint resulting from osteoarthritis. rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

This device is intended for cemented use only.

7. Device Description

The Kyocera Medical Technologies, Inc. (KMTI) Initia Knee System is a patellofemorotibial polymer/ metal/polymer semi-constrained prosthesis intended to be implanted to replace a knee joint. The system consists of femoral, tibial and patella components intended for use with bone cement. The Initia Knee System includes both posterior-stabilizing (PS) and cruciate-retaining (CR) designs.

Femoral Components

Eleven (11) sizes in CR design and 11 sizes in PS design (a total of 22 components), and for left and right sides in both designs. The femoral components are manufactured from Co-Cr-Mo alloy.

Tibial Baseplate Components

Ten (10) sizes in a keeled design, manufactured from Ti-6Al-4V alloy.

Tibial Insert Components

Seven (7) sizes of CR design and 7 sizes of PS design. The inserts will be offered in three (3) polyethylene materials: conventional UHMWPE (GUR1020), highly cross-linked UHMWPE without vitamin E, and cross-linked UHMWPE with vitamin E added.

Patella Components

Seven (7) sizes in domed, pegged design, also manufactured from conventional UHMWPE, cross-linked UHMWPE without vitamin E, and cross-linked UHMWPE with vitamin E added.

Instrumentation

Consists of general orthopedic surgical instruments for use with the system components, trial implant components, and general instruments. Most are manufactured of common stainless steels, while the tibial insert and patella trials are manufactured from medical grade polyphenylsulfone resin.

8. Substantial Equivalence Discussion

The Initia Knee System Indications for Use are identical to the predicate device's. The technological characteristics are the same or similar to those of the predicate device.

The same:

- Materials: Co-Cr-Mo (Femoral); Ti-6Al-4V (Baseplate); Highly cross-linked UHMWPE with and without vitamin E, UHMWPE GUR1020 (Inserts and Patellae)
- Cruciate-retaining and Posterior-stabilized designs

- Patellar locking mechanism
- Cemented fixation only
- Side-specific femoral configurations
- Sterilization: Gamma irradiation and Ethylene oxide
- Performance: Baseplate fatigue; Tibial Post static fracture and fatigue; Tibial baseplate locking mechanism; Femoral/Tibial constraint; Femoral/Tibial contact area / stress; Patello/Femoral contact area / stress and subluxation; Femoral fatigue (Initia Knee only)

Similar:

- Sizes:
  - Initia Knee has 11 femoral sizes compared to 9 for the A200 Knee predicate, and is not offered in a narrow size.
  - Initia Knee has 10 baseplate sizes compared to 9 for the A200 Knee predicate, and is not designed with separate left/right configurations.
  - Initia Knee has 7 tibial insert sizes compared to 3 for the A200 Knee predicate, and does not include a PS+ insert.
  - Initia Knee has 7 patella sizes compared to 5 for the A200 Knee predicate, and has domed 3-leg patella design only, whereas the predicate includes domed 3-leg and sombero designs.
- Dimensions: Initia Knee components have slightly different dimensions than the predicate's, but results of testing raise no new questions of safety and effectiveness.

Based on verification and validation test results, the minor design differences between the subject device and predicate device do not raise new questions of safety or effectiveness as compared to the predicate device.

9. Non-Clinical Performance Data

The following tests, also performed on the A200 Knee System predicate, were performed for the Initia Knee System components and found to be acceptable:

- Tibial Post Fatigue Strength (static and fatigue)
- Tibial Tray Locking Mechanism
- Tibial-Femoral Constraint
- Tibial-Femoral Contact Area/Contact Stress
- Femoral Fatigue
- Patello-Femoral Lateral Subluxation and Contact Area/Contact Stress

10. Consensus Standards

The Initia Knee System complies with the following standards:

- ASTM F1672-14 Standard Specification for Resurfacing Patellar Prosthesis
- ASTM F1814-22 Standard Guide for Evaluating Modular Hip and Knee Joint Components
- ASTM F2083-21 Standard Specification for Knee Replacement Prothesis
- ASTM F3210-22 Standard Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions
- ASTM F1800-12 Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements

- ISO 7207-2(2011/Amd 2:2020) Implants for surgery - Components for partial and total knee joint prostheses - Part 2: Articulating surfaces made of metal, ceramic and plastics materials [Including AMENDMENT 1 (2016) and AMENDMENT 2 (2020)]
- ASTM F2003-02 (2022) Standard Practice for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ANSI/AAMI ST72:2019 Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
- AAMI/ANSI/ISO 11737-1:2018 Sterilization of health care products - microbiological methods - part 1: determination of the population of microorganisms on product
- AAMI/ANSI/ISO 10993-7:2008 (R)2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
- ANSI/AAMI/ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices
- ISO 11607-1:2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming sealing and assembly processes
- ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11(2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ISO 11137-1(2006) Sterilization of health care products - Radiation - Part 1: Requirements for development validation and routine control of a sterilization process for medical devices
- ISO 11137-2(2013) Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11137-3(2017) Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development validation and routine control
- ISO 11137-4(2020) Sterilization of health care products - Radiation - Part 4: Guidance on process control
- ISO 10993-1:2018 Biological evaluation of medical devices
- ISTA 2A (2011) Packaged-Products 150 lb (68 kg) or Less - Partial Simulation Performance Tests
- ISTA 3A (2018) Packaged-Products for Parcel Delivery System Shipment 150 lb (68 kg) or Less
- ISO 15223-1 (2021) Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- ASTM D4169-23e1 Standard Practice for Performance Testing of Shipping Containers and Systems
- AAMI TIR28: 2016 (R2020) Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
- USP <85> Bacterial Endotoxins Test

11. Conclusion of Substantial Equivalence

The KMTI Initia Knee System has the same intended use as the legally marketed KMTI A200 Knee System predicate device and the same or similar technological characteristics. It has been demonstrated that differences are minor and do not raise different questions of safety and effectiveness than were raised by the predicate device. The data demonstrates that the Initia Knee System is substantially equivalent to the A200 Knee System predicate device.