October 7, 2024

Overture Orthopaedics
Jonathan Nielsen
VP of R&D
5 Peters Canyon Road
Suite 160
Irvine, California 92606

Re: K242746
Trade/Device Name: OvertureTi Knee Resurfacing 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: September 10, 2024
Received: September 11, 2024

Dear Jonathan Nielsen:

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,

Lixin Liu -S

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)*

K242746

Device Name

OvertureTi Knee Resurfacing System™

Indications for Use *(Describe)*

The OvertureTi Knee Resurfacing System™ is intended to be used in the partial replacement of the articulating surfaces of the knee in instances where, due to compartmental degenerative disease, post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity, or previous arthroplasty, only the one side of the joint is affected. This device is intended to be used with bone cement.

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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"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."

510(k) Summary

APPLICANT:

Company Name:	Overture Orthopaedics
Address:	5 Peters Canyon Road, Suite 160 Irvine, CA 92606
Telephone:	949-412-5540
Fax Number:	949-889-3837

APPLICANT CONTACT: Jonathan Nielsen

CORRESPONDENT: Overture Orthopaedics
5 Peters Canyon Road, Suite 160
Irvine, CA 92606

CORRESPONDENT CONTACT: Jonathan Nielsen

DATE PREPARED: 10 September 2024

TRADE NAME: OvertureTi Knee Resurfacing System™

CLASSIFICATION NAME: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis (21 CFR 888.3520)

COMMON NAME: Unicompartmental Knee Resurfacing System

REGULATORY CLASS: II

PRODUCT CODE: HSX

SUBSTANTIAL EQUIVALENCE:
The OvertureTi Knee Resurfacing System™ (with the Vitamin-E tibial implant) has been shown to be substantially equivalent to the legally marketed predicate based on intended use, function, design philosophy, manufacturing, and performance.

The differences between the subject device and predicate are the additions of Vitamin-E to the tibial bearing material and a visual alignment feature on the thicker edge of the implant. These changes have been assessed for their impact to existing verification and validation data and do not raise different questions of safety and effectiveness.

Primary Predicate Device: Uni Knee Resurfacing System (K221292)

There are no additional predicate devices or reference devices cited in this submission.

DEVICE DESCRIPTION:
The OvertureTi Knee Resurfacing System™ is comprised of femoral implants, tibial implants, and a set of ancillary instruments. The femoral implants are titanium and feature a spherical polished articulating surface with a titanium nitride (TiN) coating. The tibial implants are comprised of a titanium tibial tray with an integrated ultra-high molecular weight polyethylene (UHMWPE) tibial insert. The UHMWPE has Vitamin-E infused (0.1% by weight). The femoral implants and tibial trays utilize cemented pegs and porous titanium bone-contacting surfaces to allow for fixation. The femoral implant articulates against the tibial insert in a non-constrained manner.

The implants are provided in a variety of configurations and sizes to accommodate various patient anatomy. Femoral implants are offered in oblong and round configurations. The oblong femoral implants are offered in lengths ranging 25-40mm and diameters ranging 17.5-27.5mm, and the round femoral implants are offered in diameters ranging 17.5-27.5mm. The tibial implants are offered in diameters ranging 17.5-22.5mm. The implants are provided gamma sterilized and individually packaged.

MATERIALS:
The OvertureTi Knee Resurfacing System™ femoral implants are additively manufactured from Ti-6Al-4V ELI per ASTM F3001 and have a TiN coated articulating surface. The OvertureTi Knee Resurfacing System™ tibial implants are additively manufactured from Ti-6Al-4V ELI per ASTM F3001 and have a compression-molded articulating surface; the articulating surface is comprised of a highly crosslinked UHMWPE with Vitamin E (GUR 1020-E).

INDICATIONS FOR USE:
The OvertureTi Knee Resurfacing System™ is intended to be used in the partial replacement of the articulating surfaces of the knee in instances where, due to compartmental degenerative disease, post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity, or previous arthroplasty, only the one side of the joint is affected. This device is intended to be used with bone cement.

TESTING:
The following documents either report performance testing completed for the Vitamin-E tibial implants or rationales for why the release of the Vitamin-E tibial implant does not require any further testing (either performance and biocompatibility) upon leveraging K221292 verification and validation activities**:**

- Vitamin-E UHMWPE Rationale
- Characterization of Vit-E UHMWPE
- Vitamin-E Tibial Alignment Feature Test Report

In summary, rationales and testing of the OvertureTi Knee Resurfacing System™ (with the Vitamin-E tibial implant) indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSIONS:

The OvertureTi Knee Resurfacing System™ (with the Vitamin-E tibial implant) has been shown to be substantially equivalent to the legally marketed predicate based on intended use, function, design philosophy, manufacturing, and performance.