March 10, 2023

Overture Resurfacing Inc.
% Benjamin Arnold
CEO
Cor Medical Ventures, Inc.
2010 Jimmy Durante Blvd.
Suite 200
Del Mar, California 92014

Re: K221292
Trade/Device Name: Uni 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: February 8, 2023
Received: February 9, 2023

Dear Benjamin Arnold:

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

Sincerely,

Ting Song -S

Ting Song, 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221292

Device Name
Uni Knee Resurfacing System

Indications for Use *(Describe)*
The Overture Resurfacing Uni 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

**SUBMITTER:**


| | |
|---|---|
| **Company Name:** | Overture Resurfacing Inc. |
| **Address:** | 1617 3rd Avenue<br>#287284<br>New York, NY 10128 |
| **Telephone:** | 607.351.6131 |


| | |
|---|---|
| **CONTACT PERSON:** | Benjamin Arnold |
| **DATE PREPARED:** | 5/2/2022 |
| **TRADE NAME:** | Uni Knee Resurfacing System |
| **CLASSIFICATION NAME:** | Knee joint femorotibial metal/polymer non-constrained cemented prosthesis (21 CFR 888.3520) |
| **REGULATORY CLASS:** | II |
| **PRODUCT CODE:** | HSX |

**SUBSTANTIAL EQUIVALENCE:**
The Uni Knee Resurfacing System is substantially equivalent to the primary predicate device in all facets including function, design, performance, material, and intended use.

| | |
|---|---|
| Primary Predicate Device: | Unicompartmental Knee Resurfacing Prosthesis (UniCAP™) (K050373) |

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

**DEVICE DESCRIPTION:**
The Uni 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 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. The ancillary instruments are provided non-sterile and are to be sterilized by the end user.

**MATERIALS:**
The Uni Knee Resurfacing System femoral implants are additively manufactured from Ti-6Al-4V ELI per ASTM F3001 and have a TiN coated articulated surface. The Uni Knee Resurfacing System tibial implants are additively manufactured from Ti-6Al-4V ELI per ASTM F3001 and have a compression-molded UHMWPE articulating surface.

**INDICATIONS FOR USE:**
The Overture Resurfacing Uni 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.

**PERFORMANCE TESTING:**
The following bench testing was performed on the Uni Knee Resurfacing System**:**

- Range of Motion Rationale
- Tibial Tray Fatigue
- Wear Debris
- Additive Manufacturing Rationale
- Cantilever Bending Test, Femoral Implants
- Implant Stability Testing
- Tibial Tray and Insert Interlock Mechanism Test
- Characterization of Ultra-High Molecular Weight Polyethylene
- Porous Coating Characterization
- Testing the Modified Metallic Surfaces of the Implants
- Biocompatibility Rationale

In summary, rationales and mechanical testing of the Uni Knee Resurfacing System indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

**CONCLUSIONS:**
The Uni Knee Resurfacing System has shown to be substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices.