July 7, 2023

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

Re: K231253
Trade/Device Name: Overture Orthopaedics Patellofemoral System
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: April 20, 2023
Received: May 1, 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,

Lixin Liu -S

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

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)*
K231253

Device Name
Overture Orthopaedics Patellofemoral System

Indications for Use *(Describe)*
The Overture Orthopaedics Patellofemoral System is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

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.

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510(K) SUMMARY

SUBMITTER:

Company Name:	Overture Resurfacing Inc.
Address:	1617 3rd Avenue #287284 New York, NY 10128
Telephone:	607.351.6131

CONTACT PERSON:	Benjamin Arnold
DATE PREPARED:	7/7/2023
TRADE NAME:	Overture Orthopaedics Patellofemoral System
COMMON NAME:	Patellofemoral System
CLASSIFICATION NAME:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis (21 CFR 888.3540)
REGULATORY CLASS:	II
PRODUCT CODE:	KRR
Predicate Device:	Arthrosurface, Inc. HemiCAP™ Patello-Femoral Resurfacing Prosthesis (K060127)
Reference Device:	Overture Resurfacing Inc. Uni Knee Resurfacing System (K221292)

DEVICE DESCRIPTION:

The Overture Orthopaedics Patellofemoral System is comprised of trochlear implants, patellar implants, and a set of ancillary instruments. The trochlear implants are titanium and feature a polished articulating surface with a titanium nitride (TiN) coating. The patellar implants are cross-linked ultra high molecular weight polyethylene (UHMWPE) and feature a titanium pin for X-ray visualization. The trochlear and patellar implants utilize cemented pegs for immediate fixation. The trochlear implants also feature porous titanium bone-contacting surfaces.

The implants are provided in a variety of configurations and sizes to accommodate various patient anatomy. The trochlear implants are offered in long and round geometries. The long implants are offered in lengths ranging 25-40mm and widths ranging 20-35mm. The round trochlear implants are offered in diameters ranging 20-35mm. The patellar implants are offered in a domed geometry in diameters of 25mm and 30mm.

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 Overture Orthopaedics Patellofemoral System trochlear implants are additively manufactured from Ti-6Al-4V ELI per ASTM F3001 and have a TiN coated articulating surface. The Overture Orthopaedics

Patellofemoral System patellar implants are compression-molded from highly cross-linked UHMWPE and feature a titanium pin.

INDICATIONS FOR USE:
The Overture Orthopaedics Patellofemoral System is intended to be used in cemented arthroplasty in patients with osteoarthritis limited to the distal patello-femoral joint, patients with a history of patellar dislocation or patellar fracture, and those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

SUBSTANTIAL EQUIVALENCE DISCUSSION:
The Overture Orthopaedics Patellofemoral System is substantially equivalent to the predicate device in all facets including function, design, performance, material, and intended use.

The Overture Orthopaedics Patellofemoral System devices are made from similar materials and have equivalent design philosophy, sizing, configurations, fixation methods, sterilization and packaging, and surgical approach to the predicate devices. Any differences between the Overture Orthopaedics Patellofemoral System devices and the predicates are considered minor and do not raise questions concerning safety or effectiveness.

PERFORMANCE TESTING:
The following bench testing was performed on the Overture Orthopaedics Patellofemoral System**:**

- Patellofemoral Contact Area and Contact Stress Testing
- Patellofemoral Constraint Testing
- Patellofemoral Cadaveric Validation Lab
- Range of Motion Analysis
- Fatigue Strength Adoption Rationale
- Wear Testing Adoption Rationale
- Additive Manufacturing Rationale
- Characterization of UHMWPE Adoption Rationale
- Characterization of Porous Coating Adoption Rationale
- Testing the Modified Metallic Surfaces Adoption Rationale

In summary, rationales and mechanical testing of the Overture Orthopaedics Patellofemoral System indicated there are no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSIONS:
The Overture Orthopaedics Patellofemoral System is substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices.