December 23, 2022

Episurf Medical, Inc.
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
Mcra, LLC
803 7th St NW
Washington, District of Columbia 20001

Re: K221048
Trade/Device Name: Episealer® 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: December 1, 2022
Received: December 1, 2022

Dear Hollace Rhodes:

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)*
K221048

Device Name

Episealer Patellofemoral System

Indications for Use *(Describe)*

The Episealer Patellofemoral System is intended to be used in patients with osteoarthritis limited to the distal patellofemoral 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.

The device is intended for cemented fixation.

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

Device Trade Name: Episealer® Patellofemoral System

Manufacturer:
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Date Prepared: December 23, 2022

Regulation: 21 CFR 888.3540, Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prosthesis

Class: II

Product Code: KRR

Primary Predicate: Arthrosurface Patello-Femoral Arthroplasty System (K060127)

Reference Devices: Arthrosurface Patello-Femoral Arthroplasty System (K181280, K071413)
Restoris Multi Compartmental Knee (MCK) (K172326)

Indications For Use:

The Episealer Patellofemoral System is intended to be used in patients with osteoarthritis limited to the distal patellofemoral 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.

The device is intended for cemented fixation.

Device Description:

The Episealer Patellofemoral System is a patient-individualized arthroplasty device which replaces a damaged patellofemoral joint. The subject device consists of two components:

- Episealer PF
- Patellar Component

The Episealer PF component is implanted centrally in the trochlear area of the distal femur. The Patellar Component is implanted on the backside of the patella and articulates with the Episealer PF.

Predicate and Reference Devices:

Predicate: Arthrosurface Patello-Femoral Arthroplasty System (K060127)

Reference Devices: Arthrosurface Patello-Femoral Arthroplasty System (K181280, K071413), and Restoris Multi Compartmental Knee (MCK) (K172326)

Performance Testing Summary:

Wear testing of the Episealer Patellofemoral System was performed. In addition, analyses of contact area and cantilever bending strength were conducted.

A cadaver study was conducted to demonstrate that the components of the patient-matched Episealer Patellofemoral System can be accurately placed relative to the pre-planned position, with proper recession and engagement of the Episealer PF and Patellar components.

The testing, engineering analyses, and cadaver study demonstrate the ability of the Episealer Patellofemoral System to perform as intended in the target population.

Substantial Equivalence:

The Episealer Patellofemoral System is equivalent to the predicate device, the Arthrosurface Patello-Femoral Arthroplasty System, with respect to intended use, materials, geometry, range of sizes, and method of fixation. Therefore, the substantial equivalence between these two devices has been established.