November 21, 2019

Engage Surgical
Mr. Nicholas Slater
Chief Operating Officer
3225 N. Colorado St
Chandler, Arizona 85225

Re: K190439
Trade/Device Name: Engage™ Partial Knee System
Regulation Number: 21 CFR 888.3535
Regulation Name: Knee Joint Femorotibial (Uni-Compartmental) Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: NJD, HSX
Dated: October 21, 2019
Received: October 22, 2019

Dear Mr. Slater:

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,

for
William Jung, Ph.D.
Director (Acting)
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190439

Device Name
The Engage™ Partial Knee System

Indications for Use *(Describe)*
The Engage™ Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty
- As an alternative to tibial osteotomy in patients with Unicompartmental osteoarthritis.

The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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*PRAStaff@fda.hhs.gov*

*"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 for The Engage™ Partial Knee System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of substantial equivalence of The Engage™ Partial Knee System.

## A. SUBMITTERS INFORMATION

| | |
|---|---|
| **Submitter Name:** | Engage Surgical |
| **Submitter Address:** | 3225 N. Colorado Street, Chandler, AZ 85225 USA |
| **Contact Person:** | Nick Slater |
| **Title:** | Chief Operating Officer |
| **Phone Number:** | 570-713-9227 |
| **Fax Number:** | 407-641-8611 |
| **Date of Submission:** | October 21, 2019 |

## B. MANUFACTURER & DEVICE IDENTIFICATION

| | |
|---|---|
| **Manufacturer Name:** | Engage Surgical |
| **Manufacturer Address:** | 3505 Lake Lynda Drive, Suite 206<br>Orlando, Florida 32817 |
| **Device Trade Name:** | The Engage™ Partial Knee System |
| **Device Common Name:** | Unicompartmental Knee |
| **Classifications:** | 21 CFR 888.3535 – Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis<br>21 CFR 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis |
| **Product Codes:** | NJD and HSX |
| **Classification Panel:** | Orthopedic |

## C1. PRIMARY PREDICATE DEVICE

| | |
|---|---|
| **K133811** | Mako Surgical Inc.'s Restoris Porous Partial Knee System |

## C2. ADDITIONAL PREDICATE DEVICES

| | |
|---|---|
| **K033810** | Centerpulse Orthopedics, Inc.'s Natural-Knee II Unicompartmental Knee System |
| **K163700** | BodyCAD Unicompartmental Knee System |

## C3. REFERENCE DEVICES

| | |
|---|---|
| **K142066** | Stryker Spine AERO-LL Lumbar Cage System |
| **K033363** | Zimmer Unicompartmental Knee System (ZUK) |

## D. DEVICE DESCRIPTION

The Engage™ Partial Knee System is a unicompartmental knee system comprised of tibial trays, tibial inserts, tibial anchors, and femoral components. The implant geometry is optimized for the medial compartment. The Engage™ Partial Knee System permits all sizes of femur to be interchangeable with all sizes of tibial trays and associated tibial insert combinations. The tibial tray and tibial anchor are composed of Ti-6Al-4V alloy, the tibial insert is composed of UHMWPE, and the femoral component is composed of CoCrMo alloy. The tibial tray includes pegs and an engineered porous surface, while the femoral component includes pegs and a sintered porous coating; both of which are intended for biological fixation when used without bone cement and to enhance fixation when used with PMMA bone cement. The Engage™ Partial Knee System is intended for cemented or uncemented replacement of the medial compartment of the knee. The tibial anchors provide for supplemental fixation of the tibial tray when implanted without bone cement. The tibial anchor is not used when the tibial tray is implanted with bone cement.

## E. INDICATIONS FOR USE

The Engage™ Partial Knee System is intended for medial unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, including prior unicompartmental knee arthroplasty
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

The femoral component and tibial tray are intended for cementless or cemented fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. When the tibial tray is implanted without the use of bone cement, the tibial anchor should be used. When the tibial tray is implanted with bone cement, the tibial anchor should not be used.

## F. PERFORMANCE DATA

Pre-clinical performance testing was performed for the Engage™ Partial Knee System per the FDA Guidance Document "*Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA*", ASTM and ISO consensus standards, and publicly available information. The performance data presented in this 510(k) notification for the Engage™ Partial Knee System demonstrate its substantial equivalence to the identified predicate device unicompartmental knee device.

- Tibial baseplate fatigue strength per three-point bend method as described in ASTM F3140.
- Range of Motion (ROM), contact pressure, and area of tibiofemoral articulation of UHMWPE inserts per ASTM F2083. Constraint testing / analysis per ASTM F1223.
- Resistance to dislodgement of the tibial insert per ASTM F1814.
- Evaluation of the tibial baseplate and tibial anchor assembly.

- Biomechanical evaluation of the tibial tray and anchor assembly under cyclic loading.
- Evaluation of the porous fixation surfaces per the FDA guidance document “Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement”.
- Validation of additive manufacturing process for the tibial baseplate.
- Validation studies of packaging and shelf life testing.
- Bacterial endotoxins test (BET), also known as Limulus Amebocyte Lysate (LAL) testing.
- Validation of reusable instrument reprocessing parameters including sterilization with ONE TRAY® Sealed Container System (K052567).

**G. SUBSTANTIAL EQUIVALENCE**

The Engage™ Partial Knee System is substantially equivalent to the identified predicate device based on similarities in indications for use, materials, design, size, and performance data presented in this 510(k) notification.