June 10, 2021

Signal Medical Corporation
Dora Culton
Quality Assurance and Regulator Engineer
400 Pyramid Dr.
Marysville, Michigan 48040

Re: K203779
Trade/Device Name: Symmetric™ Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 4, 2021
Received: June 7, 2021

Dear Dora Culton:

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, Ph.D., R.A.C.
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)*
K203779

Device Name
Symmetric(TM) Total Knee System

Indications for Use *(Describe)*
The Symmetric(TM) Total Knee System consists of single use components intended for total knee arthroplasty with the following indications:

1. Rheumatoid arthritis,
2. Post-traumatic arthritis,
3. Osteoarthritis,
4. Degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result,
5. Failed osteotomies, unicompartmental replacement, or total knee replacement.

All components are for cemented use only.

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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05 - 510(k) Summary

I. SUBMITTER

Signal Medical Corporation
400 Pyramid Drive
Marysville, MI 48040

Ph: (810) 364-7070
Fx: (810) 364-7072

Contact Person: Dora Culton
Date Prepared: June 4, 2021

II. DEVICE

Name of Device:	Symmetric™ Total Knee System
Common or Usual Name:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	II
Product Codes:	JWH
Regulation Number:	888.3560

III. PREDICATE DEVICE

Symmetric Total Knee System, K080199
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Femoral components are cobalt chromium alloy (ASTM F75). Tibial articular inserts and patellar components are UHMWPE (ASTM F648). Tibial trays, metaphyseal and revision stems, femoral and tibial wedges and cones, and screws (K961157), are titanium (ASTM F1472). Coated cobalt chromium and titanium components feature a coating of plasma sprayed titanium (ASTM F1580).

The purpose of this 510(k) is to submit an additional sterilization method of a flexible bag system. Other descriptive details remain unchanged from the predicate.

05 - 510(k) Summary

V. INTENDED USE / INDICATIONS FOR USE

The Symmetric™ Total Knee System consists of single use components intended for total knee arthroplasty with the following indications:

1. Rheumatoid arthritis,
2. Post-traumatic arthritis,
3. Osteoarthritis,
4. Degenerative arthritis in older patients whose age, weight and activity level are compatible with an adequate long-term result,
5. Failed osteotomies, unicompartmental replacement, or total knee replacement.

All components are for cemented use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The same technological characteristics exist for both devices.

VII. PERFORMANCE DATA

The full sterilization qualification of the flexible bag sterilization vendor is included in the submission.

VIII. CONCLUSIONS

The technological characteristics/features and performance characteristics for the Symmetric Total Knee System are substantially equivalent to the legally marketed predicate device. This 510(k) is submitted for the addition of the flexible bag chamber sterilization method.