February 13, 2020

BRM Extremities
% Margeaux Rogers
Associate Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K191966
Trade/Device Name: NewPrim System
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe Joint Polymer Constrained Prosthesis
Regulatory Class: Class II
Product Code: KWH
Dated: January 16, 2020
Received: January 16, 2020

Dear Margeaux Rogers:

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 Ting Song, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
~~xxxxxxx~~ K191966

Device Name
BRM Extremities NewPrim System

Indications for Use *(Describe)*
The BRM Extremities NewPrim device is intended for use in:
- Hallux rigidus or hallux limitus;
- Painful rheumatoid arthritis;
- Hallux abducto valgus associated with arthritis;
- Unstable or painful joint from previous surgery

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

Manufacturer: BRM Extremities
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Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street, NW, Suite 1000
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: February 12, 2020

Device Trade Name: BRM Extremities NewPrim System

Device Common Name: Toe joint polymer constrained prosthesis

Classification: 21 CFR 888.3720 – Prosthesis, Toe, Constrained Polymer

Class II

Product Codes: KWH

Indications for Use:

The BRM Extremities NewPrim device is intended for use in:

- Hallux rigidus or hallux limitus;
- Painful rheumatoid arthritis;
- Hallux abducto valgus associated with arthritis;
- Unstable or painful joint from previous surgery

Device Description:

The NewPrim system is a double-stemmed, constrained, silicone prosthesis, intended to be implanted to replace the osteo-cartilaginous heads of the first metatarsophalangeal joint. The implant is designed to act as a joint spacer between the resected head of the first metatarsal and base of the proximal phalanx.

Predicate Devices:
The NewPrim system is substantially equivalent to the primary predicate RTS Flexible 1st MPJ Implant w/ Grommets (K153609) and reference predicate Integra Classic Great Toe Implant (K023562).

Substantial Equivalence:
The NewPrim System and the legally marketed predicate device have the same intended use and indications for use, similar dimensions, geometry and materials. The stems of the devices are fit into the intramedullary canals of the first metatarsal phalangeal joint. The devices are constrained and made of silicone elastomer. The devices also have proximal and distal grommets that may be used with the silicone implant.

Static tensile testing demonstrated that the static strength of the subject device is substantially equivalent to that of the reference predicate (K023562). Results of fatigue testing demonstrated that the NewPrim spacer performs as intended in fatigue displacements more extreme than expected with physiologic implant displacement. Additionally, the NewPrim System is in compliance with LAL testing requirements for orthopedic devices per AAMI ST-72 testing.