BRM Extremities Srl
% Margeaux Rogers
Director, Regulatory Affairs
Mcra, LLC
803 7th Street NW
Washington, District of Columbia 20001

April 4, 2023

Re: K220142
Trade/Device Name: BRM Digitalis Spacer
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KYJ
Dated: March 9, 2023
Received: March 9, 2023

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.04.04 12:51:22 -04'00'

Farzana Sharmin, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220142

Device Name
BRM Digitalis Spacer

Indications for Use *(Describe)*
The Digitalis Spacer MCP implants are intended for replacement of the metacarpophalangeal joint of the hand which has been damaged by:
• Osteoarthrosis;
• Rheumatoid arthritis;
• Post traumatic arthritis.

The Digitalis Spacer PIP implants are intended for replacement of the proximal interphalangeal joint of the hand which has been damaged by:
• Rheumatoid arthritis;
• Osteoarthritis;
• Ankylosed joints or those with limited range of motion which have not responded to conservative treatment;
• Non-functional joint due to inadequate bony alignment and joint space which cannot be restored by soft tissue reconstruction alone;
• Destroyed articular surface(s).

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.

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510(k) Summary – K220142

Manufacturer: BRM Extremities
Registered Office: Via Lorenzo Mascheroni 29
20145 Milano (MI) - Italy
Headquarter: Via Papa Giovanni XXIII, 9
23862 Civate (LC) - Italy

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Prepared By:
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803 7th Street NW
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: March 21, 2023

Device Trade Name: BRM Digitalis Spacer

Device Common Name: Prosthesis, Finger, Constrained Polymer

Classification: 21 CFR 888.3230 – Finger joint polymer constrained prosthesis

Class II

Product Codes: KYJ

Indications for Use:

The Digitalis Spacer MCP implants are intended for replacement of the metacarpophalangeal joint of the hand which has been damaged by:

- Osteoarthrosis;
- Rheumatoid arthritis;
- Post traumatic arthritis.

The Digitalis Spacer PIP implants are intended for replacement of the proximal interphalangeal joint of the hand which has been damaged by:

- Rheumatoid arthritis;
- Osteoarthritis;

- Ankylosed joints or those with limited range of motion which have not responded to conservative treatment;
- Non-functional joint due to inadequate bony alignment and joint space which cannot be restored by soft tissue reconstruction alone;
- Destroyed articular surface(s).

Device Description:
The Digitalis Spacer is a double-stemmed, constrained, silicone prosthesis with a hinge joint. The subject device is available in two options, one intended for use in the metacarpophalangeal (MCP) and the other for use in the proximal interphalangeal joints (PIP). The implant MCP option is intended to be implanted to replace the osteo-cartilaginous heads of the metacarpophalangeal joint an act as a joint spacer between the resected head of the head of the metacarpal at the distal head and the base of the proximal phalanx. The implant PIP option is intended to be implanted to replace the osteo-cartilaginous heads of the proximal interphalangeal joint and act as a joint spacer between the head of proximal phalanx and base of the medial phalanx.

Primary Predicate Device:
The Digitalis Spacer is substantially equivalent to the primary predicate device Ascension Silicone MCP Spacers (K022892) with respect to intended use and indications for use, similar dimensions, and geometry.

Additional Predicate Devices:
The Digitalis Spacer is substantially equivalent to the additional predicate devices Ascension PIP Spacers (K082231) and Stryker Silicone PIP & MCP (K870200 & K931588) with respect to intended use and indications for use, similar dimensions, and geometry.

Reference Device:
The Digitalis Spacer is similar to the reference device NewPrim System (K191966) with respect to material.

Discussion of Non-Clinical Testing/Performance Data:
Mechanical testing included evaluation of static strength of the silicone material as well as fatigue strength testing of the worst-case construct.

The BRM Digitalis Spacer is identical to the reference device in terms of material. Based on similarities in material and intended use, static strength testing performed on sections of the reference device components is applicable to the subject device; the static tensile strength of the BRM Digitalis Spacer is expected to exceed anticipated physiologic loading.

Fatigue testing performed on the subject device which incorporated both high and low cycle activities representative of intended physiologic use was performed according to ASTM F1781 (2021). Additionally, crack propagation was specifically analyzed as well as wear particle analysis. Additionally, the Digitalis Spacer is in compliance with LAL testing requirements for orthopedic devices per AAMI ST-72 testing.

Substantial Equivalence Conclusions:

The Digitalis Spacer 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 metacarpophalangeal and proximal interphalangeal joints. The devices are constrained and made of silicone elastomer.

Conclusions drawn from the nonclinical testing demonstrate that the BRM Digitalis Spacer is as safe, as effective, and performs as well as the legally marketed predicate device.