December 16, 2022

BRM Extremities
% Timothy Sutton
Associate, Regulatory Affairs
Mcra, LLC.
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: K222820
Trade/Device Name: BRM TOOL Screws, BIOPLAN Subtalar Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 19, 2022
Received: September 19, 2022

Dear Timothy Sutton:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K222820

Device Name
BRM Screw Family

Indications for Use *(Describe)*
BRM Tool Screws
The BRM TOOL Screws are indicated for use for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion, and bone fragment fixation appropriate with the size of the screw.

The BIOPLAN Implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- Flat foot treatment in children and adolescents
- Congenital flat foot
- Non successful long term orthopaedic treatment (shoes, insoles…)
- Tarsal coalitions
- Painfully flat foot
- Supple deformity in posterior tibial tendon dysfunction
- Paralytic flat foot
- Subtalar instability

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.

7. 510(k) Summary

Manufacturer: BRM Extremities S.r.l.
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: MCRA, LLC
803 7th Street NW
Washington, DC 20001
Phone: 202.552.5800

Date Prepared: December 14th, 2022

Device Trade Name: **BRM Screw Family**
BRM TOOL Screws
BIOPLAN Subtalar Implants

Device Common Name: Smooth or Threaded Metallic Bone Fixation Fastener

Classification: 21 CFR 888.3040 – Screw, Fixation, Bone

Class II

Product Codes: HWC

Indications for Use:
BRM TOOL Screws
The BRM TOOL Screws are indicated for use for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw.

BIOPLAN Subtalar Implants
The BIOPLAN Subtalar Implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- ***Flat foot treatment in children and adolescents***

- ***Congenital flat foot***
- ***Non successful long term orthopaedic treatment (shoes, insoles…)***
- ***Tarsal coalitions***
- ***Painfully flat foot***
- ***Supple deformity in posterior tibial tendon dysfunction***
- ***Paralytic flat foot***
- ***Subtalar instability***

Device Description:
The BRM TOOL Screws are interfragmentary compression osteosynthesis screws, i.e., devices used in surgical orthopedic interventions to provide support to the bone structure, with the aim to reduce fractures in several parts of the skeleton, particularly of bone epiphyses. The application field excludes spinal, rib cage and skull bones. The BRM TOOL Screws are available in Titanium alloy. The BIOPLAN Subtalar Implants are used for the correction of the flatfoot pathology. The BIOPLAN Subtalar Implants are available in Titanium alloy and PEEK options.

Predicate Devices and Technological Comparison:
The BRM Screw Family of devices are substantially equivalent to the primary predicate BRM TOOL Screws (K203773) and additional predicate In2Bone PIT'Stop Subtalar Implant (K170688) with respect to intended use, indications for use, design and materials (Titanium Alloy and PEEK).

Performance Testing:
Testing included static strength and fatigue strength testing, pushout and pull-out testing, as well as insertion and extraction torque testing. Results were determined to meet the pre- defined acceptance criteria per ASTM F543 and ASTM F1264. Additionally, the BRM Screw Family is in compliance with LAL testing requirements for orthopedic devices per AAMI ST-72 testing.

Substantial Equivalence Conclusion:
The BRM Screw Family and the legally marketed predicate devices have the same intended use and indications for use, similar dimensions, geometry and materials. Additionally, information presented in the Mechanical Testing section demonstrate that the screws met the pre-defined acceptance criteria per ASTM F543 and ASTM F1264.