February 2, 2021

BioPoly, LLC
% Dave McGurl
Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K203634
Trade/Device Name: BioPoly Great Toe Hemiarthroplasty Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe Joint Phalangeal (Hemi-Toe) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: December 11, 2020
Received: December 11, 2020

Dear Dave McGurl:

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., 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203634

Device Name
BioPoly Great Toe Hemiarthroplasty Implant

Indications for Use *(Describe)*

The BioPoly Great Toe Hemiarthroplasty implant is intended to be implanted to replace the distal metatarsal surface of the great toe of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

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

Device Trade Name: BioPoly Great Toe Hemiarthroplasty Implant

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Prepared by: Mr. Dave McGurl
Director, Regulatory Affairs
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Date Prepared: January 29, 2021

Classification Names: 21 CFR 888.3730
Toe joint phalangeal (hemi-toe) polymer prosthesis

Class: Class II
Product Codes: KWD

Common Name: Toe Prosthesis

Primary Predicates:
The subject devices are substantially equivalent to the following primary predicate device.

Predicate Devices

Predicate Type	Manufacturer	Device Name	K Number
Primary	Vilex	Met-Head™, Resurfacing Hemi-Arthroplasty Implant Cannulated Hemi Implants	K070052 K190543
Reference	Dow Corning H.P.	Condylar Implant	K781870

Indications for Use:
The BioPoly Great Toe Hemiarthroplasty implant is intended to be implanted to replace the distal metatarsal surface of the great toe of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement.

Device Description:
The BioPoly Great Toe Hemiarthroplasty Implant is a hemi-arthroplasty device specifically designed to restore the articular surface of the first metatarsal bone in patients with degenerative and post-traumatic arthritis.

The implant is comprised of BioPoly (UHMWPE/hyaluronic acid) direct compression molded onto a Ti-6Al-4V stem. A porous stem option is available, which additionally contains OsteoSync™ Ti, a porous titanium (CP Ti) material.

Performance Testing Summary:
Initial fixation testing was conducted and demonstrated that the fixation strength of the BioPoly Great Toe Hemiarthroplasty Implant met the predetermined acceptance criterion and exceeded the predicate fixation strength.

Shear testing was conducted and demonstrated that the interface strength of the BioPoly Great Toe Hemiarthroplasty Implant met the predetermined acceptance criterion.

Fatigue testing was conducted and demonstrated that the fatigue resistance of the BioPoly Great Toe Hemiarthroplasty Implant met the predetermined acceptance criterion.

Wear testing against cartilage was conducted and demonstrated that the wear characteristics met the predetermined acceptance criterion. The results showed significantly less wear of the BioPoly material when compared to predicate materials (CoCrMo and Silastic) against cartilage. Also, the amount of cartilage wear was significantly less when articulating with BioPoly than when articulating with CoCrMo or Silastic.

The following BioPoly Material testing was conducted:

- Tensile and impact strength testing was conducted and demonstrated that the tensile properties and impact strength of the BioPoly material meets or exceeds the Type 1 (impact strength) and Type 2 / 3 (tensile) requirements per ASTM F648.
- Fatigue crack propagation testing of the BioPoly material was conducted per ASTM E647.
- Density testing was conducted and demonstrated that the density of the BioPoly material meets the Type 1 requirements per ASTM F648.

- Oxidative index testing was conducted and demonstrated that the BioPoly material has no measurable oxidative index ("non-detectable") per ASTM F2102.
- Morphology testing per ASTM F648 showed full consolidation of the BioPoly material.
- Creep testing per ASTM D2990 showed no difference between BioPoly material and UHMWPE control creep strain and creep modulus.
- Coefficient of Friction testing against cartilage was conducted and demonstrated that the BioPoly material CoF with cartilage is significantly lower than that of CoCrMo, silicone, and UHMWPE.
- Pin on disc (POD) testing was conducted and demonstrated that the wear rate of BioPoly material against cobalt chrome is significantly less than that of UHMWPE control.
- Enzyme degradation testing was conducted and demonstrated that the BioPoly material in its final form is not degraded in the presence of hyaluronidase enzyme.

Bacterial Endotoxin Testing was performed using the Limulus Amebocyte Lysate (LAL) method (ANSI/AAMI ST72:2011/(R)2016, USP<161>, USP <85>, EP 2.6.14, and JP 4.01) and the measured endotoxin levels met the predetermined acceptance criteria. The measured levels were <0.0677 EU/device.

Sterilization and Cleaning:
The BioPoly Great Toe Hemiarthroplasty Implant is provided sterile by ethylene oxide gas. The reusable instruments are provided non-sterile and are required to be steam sterilized prior to use.

Substantial Equivalence Summary:
The BioPoly Great Toe Hemiarthroplasty Implant is substantially equivalent to the predicate device with regards to articular surface area, fixation volume, intended use, and indications. The addition of a porous fixation surface does not raise new types of safety and effectiveness questions, nor are there new technological issues.

Conclusion:
The information and performance data demonstrate that the device is as safe, as effective, and performs as well as or better than the primary predicate device. The subject BioPoly Great Toe Hemiarthroplasty Implant is substantially equivalent to the predicate device (K070052 and K190543), with respect to indications, design, materials, function, and performance.