BioPoly, LLC
Jacob Alumbaugh
Senior Product Development Engineer
7136 Gettysburg Pike
Fort Wayne, Indiana 46804

March 13, 2024

Re: K233592
Trade/Device Name: BioPoly Radial Head Implant
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: February 20, 2024
Received: February 21, 2024

Dear Jacob Alumbaugh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.03.13 16:24:43 -04'00'

for: Farzana Sharmin, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233592

Device Name

BioPoly Radial Head Implant

Indications for Use *(Describe)*

The BioPoly Radial Head Implant is indicated for:
• Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and or proximal radio-ulnar joint with:
  o joint destruction and/or subluxation visible on x-ray; and/or
  o resistance to conservative treatment
• Primary replacement after fracture of the radial head
• Symptomatic sequelae after radial head resection
• Revision following failed radial head arthroplasty

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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510(k) #: K233592

510(k) Summary

Prepared on: 2024-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BioPoly, LLC
Applicant Address	7136 Gettysburg Pike Fort Wayne IN 46804 United States
Applicant Contact Telephone	2604172209
Applicant Contact	Dr. Schwartz Herb
Applicant Contact Email	herb@biopolyortho.com
Correspondent Name	BioPoly, LLC
Correspondent Address	7136 Gettysburg Pike Fort Wayne IN 46804 United States
Correspondent Contact Telephone	2176638048
Correspondent Contact	Mr. Alumbaugh Jacob
Correspondent Contact Email	jacob@biopolyortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BioPoly Radial Head Implant
Common Name	Elbow joint radial (hemi-elbow) polymer prosthesis
Classification Name	Prosthesis, Elbow, Hemi-, Radial, Polymer
Regulation Number	888.3170
Product Code	KWI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183618	Revolution Radial Head	KWI
K132735	Axia Radial Head System	KWI
K203634	BioPoly Great Toe Hemiarthroplasty Implant	KWD
K222964	BioPoly Lesser Toe Hemiarthroplasty Implant	KWD

Device Description Summary

21 CFR 807.92(a)(4)

The BioPoly Radial Head Implant is a hemiarthroplasty device designed to restore the articular surface and spacing of the proximal head of the radius in patients following fracture, resection, and/or degenerative disability. The implant is supplied with head diameters of 20mm, 23mm, and 26mm; and stem diameters of 6mm, 7mm, 8mm, and 9mm with +0mm, +3mm, and +6mm height offsets for

selection by the physician.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The BioPoly Radial Head Implant is indicated for:
• Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and or proximal radio-ulnar joint with:
  o joint destruction and/or subluxation visible on x-ray; and/or
  o resistance to conservative treatment
• Primary replacement after fracture of the radial head
• Symptomatic sequelae after radial head resection
• Revision following failed radial head arthroplasty

Indications for Use Comparison 21 CFR 807.92(a)(5)

The BioPoly Radial Head has identical Indications for Use to the predicate device

Technological Comparison 21 CFR 807.92(a)(6)

Technological Characteristics:
The BioPoly Radial Head Implant has the following identical features to the Ignite Orthopedics Revolution Radial Head primary predicate:
• Method of Fixation (none - uncemented fixation)
• Articulating Geometry (concave spherical surface)
• Stem Design
• Head diameters (offered within the range of sizes of the predicate)
• Height Offset
• Site Preparation

There are four differences between the subject and predicate devices: the implant materials, the head-to-stem connection, the head diameters, and the stem sizes, but these differences do not raise different questions of safety and effectiveness. Both the subject and predicate devices are hemiarthroplasty devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Shear testing was conducted and demonstrated that the head-to-stem interface strength of the BioPoly Radial Head Implant met the predetermined acceptance criterion.

Fatigue testing was conducted and demonstrated that the fatigue resistance of the BioPoly Radial Head Implant met the predetermined acceptance criterion.

Wear testing against cartilage was conducted and demonstrated that the wear characteristics met the predetermined acceptance criterion.

Wear testing against CoCr was conducted and demonstrated that the risks of wear-through, cracking, or delamination are minimized through the lifetime of the device.

The BioPoly Material was characterized according to the FDA guidance and standards including:
• Tensile and impact strength testing per ASTM F648
• Fatigue crack propagation per ASTM E647
• Density testing per ASTM F748
• Oxidative index testing per ASTM F2102
• Morphology testing per ASTM F648
• Creep testing per ASTM D2990
• Coefficient of Friction testing
• Pin on disc (POD) testing
• Enzyme degradation testing

The subject BioPoly Radial Head implant is substantially equivalent to the predicate device (K183618) with respect to indications, design, materials, function, and performance.