September 30, 2022

Theken Companies
℅ Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre-Dame-de-L'lle-Perrot, Quebec J7V-7P2
Canada

Re: K220336
Trade/Device Name: Mg-PSZ Ceramic Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, OQG, LZO, OQI
Dated: August 15, 2022
Received: August 16, 2022

Dear Robert Poggie:

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

Limin Sun, Ph.D.
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)*

K220336

Device Name

Mg-PSZ Ceramic Femoral Head

Indications for Use *(Describe)*

The iNSitu Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The iNSitu Total Hip System femoral stems are intended for cementless fixation. The iNSitu Total Hip System acetabular cup is intended for cementless fixation. The porous structured surfaces provide biological fixation in a cementless application.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following 510(k) Summary is provided in accordance with 21 CFR 807.92.

510(k) Owner and Registration

Owner's Name:	Theken Companies, LLC Subsidiary: NextStep Arthropedix
Address:	1800 Triplett Blvd., Akron, OH 44306
Phone Number:	(330) 733-7600
Fax Number:	(330) 733-7602
Date Summary Prepared:	August 31, 2022
Establishment Registration Number:	3002498892

510(k) Contact

Contact:	BioVera, Inc.
Address:	Notre-Dame-de-L'Ile-Perrot, (QC), J7W-3J6, Canada
Phone and Fax Number:	514-901-0796
Contact Person:	Robert A Poggie, PhD

Subject Device Name and Classification

Device Trade Name:	Mg-PSZ Ceramic Femoral Head
Device Common Name:	Femoral Head
Primary predicate device:	NextStep Arthropedix Biolox Delta ceramic femoral head, K161184
Additional predicate devices:	BioPro Ziralloy modular ceramic femoral head, K912641, K925682 NextStep Arthropedix Biolox Delta ceramic femoral head, K172501, K192071, K191936
Regulation Number and Description:	21 CFR 888.3358 21 CFR 888.3353
Device Class:	Class II
Product Codes: Subsequent Product Codes:	LPH OQG, LZO, OQI
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate Devices

The NextStep Arthropedix Biolox Delta ceramic femoral head is the primary predicate device, which is part of the iNSitu Total Hip system that includes femoral hip stems, acetabular cups, UHMWPE acetabular liners, bone screws, and CoCr and ceramic femoral heads (K161184, K172501, K192071, K191936). The subject device Mg-PSZ ceramic femoral head is made from the same material as the additional predicate device, the BioPro Ziralloy modular ceramic femoral head (K912641, K925682).

Device Description

The subject device Mg-PSZ Ceramic Femoral Head is manufactured from Zirconia Mg-PSZ ceramic material, which is the same material that comprises the predicate BioPro Ziralloy modular ceramic head. The subject device Mg-PSZ Ceramic Femoral Heads, including all sizes and offsets, have the same or similar design features and indications for use as the

primary predicate device (Biolox Delta ceramic femoral head). The NextStep Arthropedix Mg-PSZ Ceramic Femoral Heads are packaged and sterilized using identical processes as the primary predicate device Biolox Delta femoral heads.

Intended Use

The iNSitu Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The iNSitu Total Hip System femoral stems are intended for cementless fixation. The iNSitu Total Hip System acetabular cup is intended for cementless fixation. The porous structured surfaces provide biological fixation in a cementless application.

Summary of Technological Characteristics

The subject device Mg-PSZ Ceramic Femoral Heads, including all sizes and offsets, have the same or similar design features and indications for use as the primary predicate device (Biolox Delta ceramic femoral head). The main difference between the primary predicate and subject device ceramic heads is the subject device is manufactured from Zirconia Mg-PSZ ceramic, while the primary predicate device is manufactured from Biolox Delta ceramic. The Zirconia Mg-PSZ material that comprises the subject device Mg-PSZ Ceramic Femoral Head is identical to the material that comprises the predicate BioPro Ziralloy modular ceramic head. The NextStep Arthropedix Mg-PSZ Ceramic Femoral Heads are packaged and sterilized using the same processes as the primary predicate device Biolox Delta femoral heads. The subject device is substantially equivalent to the predicate device based on comparisons of intended use, materials, and technological characteristics.

Performance Testing

Preclinical performance testing was conducted on NextStep Arthropedix Mg-PSZ Ceramic Femoral Heads to evaluate the device strength and performance characteristics and demonstrate substantial equivalence. The results demonstrated that the NextStep Arthropedix Mg-PSZ Ceramic Femoral Head exhibits appropriate mechanical and performance characteristics for total hip joint replacement and is substantially equivalent to the predicate devices.

- Testing of the ceramic femoral heads was conducted per ISO7206-10 and ASTMF2345 for:
    - Static Burst-Strength Testing
    - Fatigue Testing
    - Static Burst-Strength, Post-Fatigue Testing
- Disassembly testing of the femoral head/femoral taper was conducted per ISO7206-10 and ASTM F2009, and torque testing according to ISO 7206-13 for:
    - Static Pull-Off (Axial) Strength
    - Static Torque-Off/Strength
- The iNSitu Mg-PSZ Ceramic Femoral Head was tested per the material requirements specified in ASTM F2393.

Engineering analysis and mechanical testing of the subject and primary predicate devices demonstrated that the difference in ceramic material and subtle design differences in tapers did not result in new and/or adverse changes in performance characteristics.

Bacterial endotoxin testing met the acceptable endotoxin limits as stated in the FDA Guidance, “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,” “Pyrogen and Endotoxins Testing: Questions and Answers,” and ANSI/AAMI ST72.

Conclusions

A comparison of technological characteristics and performance testing demonstrate that the NextStep Arthropedix Mg-PSZ Ceramic Femoral Head is substantially equivalent to the cited predicate devices.