August 30, 2019

Theken Companies, LLC
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de L'lle Perrot, J7V7P2 CA

Re: K192071
Trade/Device Name: iNSitu Total Hip System
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: July 31, 2019
Received: August 2, 2019

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 Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192071

Device Name

iNSitu Total Hip System

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 stem is 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.

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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 29, 2019
Establishment Registration Number:	3002498892

510(k) Contact

Contact:	BioVera, Inc.
Address:	Notre-Dame-de-L'lle-Perrot (QC) J7V 7P2, CA
Phone Number:	514-901-0796
Fax Number:	514-901-0796
Contact Person:	Robert A Poggie, PhD

Device Name and Classification

Device Trade Name:	iNSitu Total Hip System
Device Common Name:	Total Hip Replacement
Regulation Number and Description:	21 CFR 888.3358 21 CFR 888.3353
Device Class:	Class II
Product Codes:	LPH OQG LZO OQI
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate

This Special 510(k) submission is to add a line extension, specifically a dual-tapered (Blade) Femoral Stem, to the iNSitu Total Hip System (K161184/K172501).

Company	Device Name	510(k) Number(s)	Clearance Date
Theken	iNSitu Total Hip System	K161184	10/14/2016
Theken	iNSitu Total Hip System	K172501	09/21/2017

Device Description

The subject device of this 510(k) notification is the Blade Femoral Stem, which is a line extension to the iNSitu Total Hip System. The Blade Femoral Stem is a collarless dual-tapered wedge designed for biologic fixation. The neck is polished and narrowed in the anterior-posterior dimension to reduce the potential for impingement with the liner and to increase the range of motion (ROM), while maintaining flexural rigidity. The proximal portion of the stem possesses a porous structured commercially pure (CP) titanium coating for biologic fixation with bone. The distal portion of the hip stem has a smooth satin finish. There is a range of sizes that proportionally increase in diameter, stem length, and neck offset to accommodate a range of human hip anatomy. The range of stem sizes is offered in both standard and lateralized neck configurations. The Blade Femoral Stem is made from titanium alloy conforming to ASTM F136.

The iNSitu Total Hip System includes a family of femoral stems (including the predicate iNSitu Femoral Stems and the subject Blade Femoral Stems), femoral head components, UHMWPE acetabular liners, acetabular cups, acetabular hole covers, optional acetabular screws, instruments, and sterilization cases. With the exception of the subject line extension Blade Femoral Stem, all other components of the subject device are identical to the predicate devices cleared in K161184 and K172501. The implants are packaged in single use, sterile packages with a 5-year shelf life and the re-usable instruments are contained in sterilization cases intended for steam sterilization.

Indications for 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 stem is 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 line extension of new sizes (iNSitu Total Hip System Blade Femoral Stem) are cleaned, packaged, and sterilized using the same processes as the family of femoral stems in the iNSitu Total Hip System (K161184/K172501). The subject Blade Femoral Stem includes additional stem length options, a modified proximal cross-section, and a new coating application method. The new sizes represented in the subject Blade Femoral Stems are substantially equivalent to the original iNSitu Total Hip System (K161184/K172501) based on comparisons of intended use, design features, and technological characteristics.

Performance Testing

Performance testing was conducted on the subject iNSitu Total Hip System Blade Femoral Stems to evaluate the device and to demonstrate substantial equivalence to the legally marketed predicate. The results confirm that the subject Blade Femoral Stem components are substantially equivalent to the predicate femoral stems.

- Distal fatigue testing of the worst-case Blade Femoral Stem was conducted.
- Proximal fatigue testing of the neck region of the worst-case Blade Femoral Stem was conducted.

Conclusions

The subject iNSitu Total Hip System Blade Femoral Stems are manufactured from similar materials and have the same indications for use as the predicate hip systems (K161184/K172501). A comparison of technological characteristics and performance testing demonstrate the iNSitu Total Hip System Blade Femoral Stems is substantially equivalent to the predicate system (K161184/K172501).