



Theken Companies, LLC
% Robert A. Poggie, Ph.D.
President
BioVera, Inc.
65 Promenade Saint-Louis
Notre-Dame-De-I'lle-Perrot, Quebec, J7V 7P2, Canada

August 20, 2019

Re: K191936

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 17, 2019

Received: July 19, 2019

Dear Dr. 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,

Vesa Vuniqui
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

Indications for Use

510(k) Number (if known)

K191936

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.

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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 9, 2019
Establishment Registration Number:	3002498892

510(k) Contact

Contact:	BioVera, Inc.
Address:	Notre-Dame-de-L'Ile-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 multi-holed acetabular cup to the iNSitu Total Hip System (K161184/K172501). The Primary Predicate Device for this system is K161184.

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 NextStep Arthropeidix Total Hip Replacement System includes a family of femoral stems, femoral head components, acetabular UHMWPE liners, acetabular cups (including solid, 3-holed, and the subject multi-holed), acetabular hole covers, optional acetabular screws, instruments, and sterilization cases (K161184/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 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 multi-holed acetabular cups are manufactured from the same materials and processes as the family of acetabular cups in the original iNSitu Total Hip System (K161184/K172501). All iNSitu Total Hip System components, including the subject multi-holed acetabular cup, are cleaned, packaged and sterilized using the same processes as previously described in K161184/K172501. The subject multi-holed acetabular cup is substantially equivalent to the original iNSitu Total Hip System (K161184/K172501) acetabular cup but includes multi-holed options for fixation into the acetabulum. The subject multi-holed acetabular cup is equivalent to the original acetabular cup based on comparisons of intended use, design features, and technological characteristics.

Performance Testing

Performance testing was conducted on the iNSitu Total Hip System multi-holed acetabular cup to evaluate the device and to demonstrate substantial equivalence. The results confirm that the multi-holed acetabular cup components are substantially equivalent to the predicate acetabular cup.

- 2-point fatigue testing was performed on the multi-holed acetabular cup to show substantial equivalence to the predicate device.
- Risk based EO sterilization was performed to document that the newly introduced iNSitu Multi-Holed Acetabular Cup did **not** present a new worst-case scenario, and therefore included into the documentation for the existing sterilization process for the predicate device (K161184/K172501).

Conclusions

The iNSitu Total Hip System multi-holed acetabular cup has the same indications for use as the iNSitu Total Hip System acetabular cup predicate device. A comparison of technological characteristics and performance testing demonstrates that the NextStep Arthropeidix iNSitu Total Hip System multi-holed acetabular cup is substantially equivalent to the predicate system (K161184/K172501).