Theken Companies, LLC
% Bob Poggie
President
BioVera
65 Promenade Saint-Louis
Notre-Dame-de-L'lle-Perrot, QC, J7V 7P2 CANADA

September 17, 2019

Re: K191297
Trade/Device Name: iNSitu Bipolar Hip System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: August 19, 2019
Received: August 20, 2019

Dear Bob 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)* K191297

Device Name

iNSitu Bipolar Hip System

Indications for Use *(Describe)*

The iNSitu Bipolar Hip System is intended for use in combination with the iNSitu Total Hip System Femoral Stems for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revisions procedures where other devices or treatments for these indications have failed

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)

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1. 510(k) Summary

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

1.1 510(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 12, 2019
Establishment Registration Number:	3002498892

1.2 510(k) Contact

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

1.3 Device Name and Classification

Device Trade Name:	iNSitu Bipolar Hip System
Device Common Name:	Hemi-hip prothesis, uncemented
Regulation Number and Description:	21 CFR 888.3390
Device Class:	Class II
Product Codes:	KWY
Advisory Panel:	87 (Orthopedic)

1.4 Legally Marketed Predicate

NextStep Arthropedix is utilizing the BioPro Bipolar Head as a predicate device (K082705/K100761). The iNSitu Bipolar Hip System features component designs, materials, indications and manufacturing methods that are identical to the BioPro Bipolar Head.

	iNSitu Bipolar Hip System	**BioPro Bipolar Head**
510(K) Number	K191297	K082705/K100761
FDA Product Code	KWY	KWY
DESIGN		
Head-Liner-Shell	CoCr-UHMWPE-CoCr	CoCr-UHMWPE-CoCr
Head Outer Diameter	38 to 60 mm in 1 mm increments	38 to 60 mm in 1mm increments
Self-aligning (eccentric head)	Yes	Yes
Liner Inner Diameter	22.225 or 28 mm	22.225 or 28mm
Liner-Head Assembly	Head snap-fit into bipolar liner	Head snap-fit into bipolar liner
UHMWPE retention	Yes	Yes
MATERIALS		
Outer Shell	Cobalt chromium (ASTM F75)	Cobalt chromium (ASTM F75)
Liner and Retention Ring	UHMWPE (ASTM F648), Ti-6Al-4V (ASTM F136), EO sterilized (not highly crosslinked)	UHMWPE (ASTM F648) and Ti-6Al-4V (ASTM F136), EO sterilized (not highly crosslinked)
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Hip System Compatibility	iNSitu Total Hip System (K161184/K172501)	BioPro PSL Hip System (K922500)

1.5 Device Description

The iNSitu Bipolar Hip System consists of a factory assembled UHMWPE (ASTM F648) liner in a cobalt chrome (ASTM F75) outer shell, and UHMWPE (ASTM F648) retention ring with a Ti-6Al-4V ELI (ASTM F136) spring. These Bipolar Heads include outer diameters ranging from 38 to 60 mm, in 1 mm increments, to properly fit the patient anatomy. The smaller Bipolar Heads (38 to 43 mm) have an inner diameter that mates with the subject 22mm diameter Femoral Head; the larger Bipolar Heads (44 to 60 mm) have an inner diameter that mates with the previously cleared 28 mm diameter Femoral Head. The iNSitu Bipolar Hip System may be used in conjunction with an iNSitu Total Hip System Femoral Stem (K161184/K172501) for hemiarthroplasty.

1.6 Intended Use

The iNSitu Bipolar Hip System is intended for use in combination with the iNSitu Total Hip System Femoral Stems for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revisions procedures where other devices or treatments for these indications have failed

1.7 Summary of Technological Characteristics

The iNSitu Bipolar Hip System has an identical design and is manufactured from the same materials as the predicate device system. The iNSitu Bipolar Hip System components are packaged and sterilized using similar processes. The subject system is substantially equivalent to the predicate based on comparisons of intended use, design features, and technological characteristics.

1.8 Performance Testing

Extensive preclinical performance testing was conducted, and substantial equivalence determined per K082705 and K100761. The components of the subject device are identical to the predicate BioPro Bipolar Head device, and therefore the predicate device testing demonstrates substantial equivalence for the subject device. The results confirm that all components of the iNSitu Bipolar Hip System exhibit the appropriate mechanical characteristics for hip hemi-arthroplasty and are substantially equivalent to the predicate devices. Range of motion testing was performed using the iNSitu Bipolar Head and the iNSitu Total Hip System Femoral Stems (K161184/K172501).

The following tests were performed using the BioPro Bipolar Head, which is identical to the iNSitu Bipolar Hip System.

- Push-Out and Lever-Out Strength
- Assembly Forces

1.9 Conclusions

The iNSitu Bipolar Hip System is identical to the predicate BioPro Bipolar Head (K082705/K100761). The subject device has the same design features, materials and indications for use as the predicate devices. The testing performed for the predicate and subject devices indicate that the subject iNSitu Bipolar Hip System is substantially equivalent to the predicate BioPro Bipolar Head.