DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Theken Companies, LLC
% Mrs. Hollace Rhodes
Director, Orthopedic Regulatory Affairs
Musculosketal Clinical Regulatory Advisors, LLC (MCRA)
1331 H Street N.W., 12th Floor
Washington, District of Columbia 20005

October 14, 2016

Re: K161184
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: September 13, 2016
Received: September 14, 2016

Dear Mrs. Rhodes:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161184

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:	October 14, 2016
Establishment Registration Number:	Not yet registered

510(k) Contact

Contact:	Musculoskeletal Clinical Regulatory Advisers, LLC
Address:	1331 H Street NW, 12th Floor, Washington DC, 20005
Phone Number:	(202) 552-5800
Fax Number:	(202) 552-5798
Contact Person:	Hollace Saas Rhodes

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
Classification Product Code:	LPH OQG LZO OQI
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate

NextStep Arthropedix is utilizing these predicates to demonstrate substantial equivalence to a legally marketed predicate. The Pipeline RESTORIS® Hip System is considered the primary predicate (same indications for use) and the Consensus TaperSet™ Stem and CS2™ Acetabular System are included for performance comparisons.

Company	Device Name	510(k) Number(s)	Clearance Date
Pipeline	Restoris Stem and Restoris PST Cup	K131237	6/13/2013
Consensus	TaperSet Stem and CS2 Cup	K121935, K141043	9/10/2012, 5/19/2014

Device Description

The iNSitu Total Hip Replacement System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular cups (additively manufactured), acetabular liners (Vitamin E polyethylene), acetabular bone screws, screw hole covers for the screw holes in the acetabular cups, and apical hole covers for the apical hole in the acetabular cups.

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 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 iNSitu Total Hip System is manufactured from titanium alloy. The iNSitu Total Hip System components are packaged and sterilized using similar processes. The subject system is substantially equivalent to the predicates based on comparisons of intended use, design features, and technological characteristics.

Performance Testing

Extensive preclinical performance testing was conducted on the iNSitu Total Hip System to evaluate the device and to demonstrate substantial equivalence. The results confirm that all components of the iNSitu Total Hip System exhibit the appropriate mechanical characteristics for total hip joint replacement, and are substantially equivalent to the predicate devices.

- Modular acetabular component disassembly testing was conducted. Liner push-out, offset pull-out, and torsional testing was conducted on worst-case sizes.
- Testing of the torsional and fixation strength and insertion and removal torque of the iNSitu acetabular bone screws was conducted.
- Physical, mechanical, thermal, cross-link, and oxidation properties of the iNSitu highly cross-linked vitamin E stabilized UHMWPE were characterized.
- Hip wear simulator testing was conducted on the worst-case components of the iNSitu Total Hip System.

- Impingement testing was conducted on the worst-case components of the iNSitu Total Hip System.
- The range of motion of the iNSitu Total Hip System was evaluated in flexion/extension, abduction/adduction, and internal/external rotation.
- Characterization of the porous structured titanium was conducted in accordance with FDA Guidance "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement."
- The physical and mechanical properties of the iNSitu AM titanium alloy solid implant substrate (non-porous base material) were fully characterized.
- An unsupported fatigue test was conducted on the iNSitu acetabular cup.
- Mechanical and fatigue testing of the ceramic femoral heads was conducted.
- Disassembly testing of the femoral head/femoral taper was conducted with both CoCr and ceramic femoral heads.
- Fatigue testing of the worst-case femoral hip stem was conducted.
- Fatigue testing of the neck region of the worst-case femoral hip stem was conducted.
- The Bacterial Endotoxins Test (BET), chromogenic kinetic method, was performed.

Conclusions

The iNSitu Total Hip System has the same indications for use as predicate hip systems. A comparison of technological characteristics and performance testing demonstrates that the iNSitu Total Hip System is substantially equivalent to the predicate systems.