September 13, 2024

NextStep Arthropedix
Garrett Spurgeon
VP - Compliance, Regulatory, & Strategy
1800 Triplett Blvd
Akron, Ohio 44306

Re: K241875
Trade/Device Name: TheRay Collared and Collarless Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH, KWY, OQG, LZO, OQI
Dated: September 5, 2024
Received: September 5, 2024

Dear Garrett Spurgeon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Limin Sun -S

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)*
K241875

Device Name
TheRay Collared and Collarless Femoral Stem

Indications for Use *(Describe)*
TheRay Collared and Collarless 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.

TheRay Collared and Collarless Total Hip System femoral stems are intended for cementless fixation. The acetabular cup is intended for cementless fixation. The porous structured surfaces on the acetabular cup provide biological fixation in a cementless application.

The iNSitu Bipolar Hip System is intended for use in combination with the iNSitu Total Hip System Femoral Stem or TheRay Collared or Collarless Femoral Stem 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;
• Revision 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:	9/12/2024
Establishment Registration Number:	3002498892

510(k) Contact

Contact:	Theken Companies
Address:	1800 Triplett Blvd., Akron, OH 44306
Phone Number:	330-733-7600
Fax Number:	330-733-7600
Contact Person:	Garrett Spurgeon

Device Name and Classification

Device Trade Name:	TheRay Collared and Collarless Femoral Stem
Device Common Name:	Femoral Stem
Regulation Number and Description:	21 CFR 888.3353
Device Class:	Class II
Product Codes:	MEH KWY OQG LZO OQI
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate

The DePuy-Synthes Actis Duofix Hip Prosthesis is considered the primary predicate (similar indications for use), while the NextStep Arthropedix iNSitu Total Hip System and the NextStep Arthropedix iNSitu Bipolar Hip System are considered reference devices and included for indications for use and performance comparisons.

Predicate	Company	Device Name	510(k) Number(s)	Clearance Date
Primary Predicate	DePuy Synthes	Actis	K150862	9/25/2015
Reference Devices	NextStep Arthropedix	iNSitu Total Hip System	K161184	10/14/2016
		iNSitu Bipolar Hip System	K191927	9/17/2019
		iNSitu Total Hip System	K191936	8/20/2019

Device Description

TheRay Collared and Collarless Hip System includes the new subject femoral stems, along with previously cleared femoral heads (K161184, K220336), acetabular cups (additively manufactured – K161184 and K191936), acetabular liners (vitamin E polyethylene – K161184), acetabular bone screws (K161184), screw hole covers for the screw holes in the acetabular cups (K161184), and apical hole covers for the apical hole in the acetabular cups (K161184). The subject femoral stem implant features a forged triplaner Ti-6Al-4V ELI substrate and an applied dual coating comprised of plasma-sprayed commercially pure titanium (CPTi) and hydroxyapatite (HA). The collared version of the subject TheRay Femoral Stem features a collar on the medial aspect of the stem above the coating that is designed to seat on the native resected calcar. The collarless version of the subject TheRay Femoral Stem is identical to the collared version, less the medial collar.

The iNSitu Bipolar Hip System has been previously cleared for use in K191297 and 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 a 22mm diameter Femoral Head; the larger Bipolar Heads (44 to 60 mm) have an inner diameter that mates with a 28 mm diameter Femoral Head. The iNSitu Bipolar Hip System may be used in conjunction with the subject TheRay Collared and Collarless Hip System Femoral Stems.

Indications for Use:

TheRay Collared and Collarless 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.

TheRay Collared and Collarless Total Hip System femoral stems are intended for cementless fixation. The acetabular cup is intended for cementless fixation. The porous structured surfaces on the acetabular cup provide biological fixation in a cementless application.

The iNSitu Bipolar Hip System is intended for use in combination with the iNSitu Total Hip System Femoral Stem or the TheRay Collared or Collarless Femoral Stem 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;
- Revision procedures where other devices or treatments for these indications have failed.

Summary of Technological Characteristics

TheRay Collared and Collarless Femoral Stem is manufactured from the same materials as the predicate stems (substrate – Ti-6Al-4V ELI, coating – CPTi + HA) and feature similar stem lengths, offsets, taper specifications, and head centers as the primary predicate and reference devices. TheRay Collared and Collarless Femoral Stems have identical indications and packaging configurations as the reference devices. The subject stem is therefore 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 subject TheRay Collared and Collarless Femoral Stem to evaluate the device and to demonstrate substantial equivalence. The results confirm that the TheRay Collared and Collarless Femoral Stem exhibits substantially equivalent performance compared to the predicate devices.

- Range of Motion (ROM) evaluation (ISO 21535)
- Distal stem fatigue testing (ISO 7206-4)
- Neck fatigue testing (ISO 7206-6)
- Femoral head disassembly performance engineering rationale
- Biocompatibility testing (ISO 10993, ANSI-AAMI ST72, ANSI-AMMI ST98, USP <643>) and rationale

Conclusions

TheRay Collared and Collarless Femoral Stem has the same indications for use as predicate hip systems. A comparison of technological characteristics and performance testing demonstrates that TheRay Collared and Collarless Hip Stem is substantially equivalent to the predicate stems.