June 5, 2026

Nextstep Arthopedix, LLC
Garrett Spurgeon
VP - Compliance, Regulatory, and Strategy
1800 Triplett Blvd
Akron, Ohio 44306

Re: K243192
Trade/Device Name: iNSitu Lateralized Acetabular Liners, iNSitu Femoral Stems with Plasma Sprayed CPTi Coating
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, KWY, MEH
Dated: May 6, 2026
Received: May 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243192

Device Name
iNSitu Lateralized Acetabular Liners, iNSitu Femoral Stems with Plasma Sprayed CPTi Coating

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 stems are 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.

TheRay Collared and Collarless 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 for cemented or 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.

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:	6/4/2026
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:	iNSitu Lateralized Acetabular Liners, iNSitu Femoral Stems with Plasma Sprayed CPTi Coating
Common Name:	Acetabular Liner, Femoral Stem
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulation Number:	21 CFR 888.3358 21 CFR 888.3353
Product Codes:	LPH OQG LZO OQI KWY MEH
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate

The iNSitu Total Hip System (K161184 / K172501 / K191936) is the primary predicate device and included for indications for use and performance comparisons. The iNSitu Bipolar Hip System (K191297) is an additional predicate.

Device Description

iNSitu Lateralized Acetabular Liners:
The subject iNSitu Lateralized Acetabular Liners are manufactured from the identical material used to manufacture devices cleared in K161184. The devices are also cleaned, packaged, and sterilized in an identical fashion. The subject devices are a line extension to the existing Neutral, Facechanging, and Hooded Acetabular Liner configurations. The subject iNSitu Lateralized Acetabular Liners feature an additional 5mm of UHMWPE material at the apical dome, which allows the surgeon to add offset to the joint reconstruction from the acetabular side of the prosthesis.

iNSitu Femoral Stems with Plasma Sprayed CPTi Coating:
The subject iNSitu Femoral Stems with plasma sprayed CPTi coating are geometrically identical to the devices reviewed by FDA in K161184 and K172501. The devices are also cleaned, packaged, and sterilized in an identical fashion. The only difference is the application method of the CPTi coating which allows NextStep Arthropedix to manufacture the iNSitu Femoral Stems with either asymmetric CPTi sintered bead or plasma sprayed CPTi coatings.

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 stems are 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.

TheRay Collared and Collarless 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 for cemented or 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.

Indications for Use Comparison:

The subject iNSitu Femoral Stems with plasma-sprayed CPTi coating and Lateralized Acetabular Liners) have identical indications for use to the predicates: iNSitu Total Hip System (K161184, K172501, K191936), the iNSitu Bipolar Hip System (K191297), and the TheRay Collared and Collarless Hip System (K241875).

Summary of Technological Characteristics

The subject iNSitu Femoral Stems with plasma-sprayed CPTi coating feature the identical geometry, sizes, indications, packaging, and sterilization as the femoral stems cleared in K161184/K172501. Only the coating application method is different.

The subject Lateralized Acetabular Liners feature the identical locking mechanism, material, indications, ackaging, and sterilization as the acetabular liners cleared in K161184/K191936. The addition of the material at the apical dome provides surgeons with additional offset options.

Performance Testing

Preclinical performance testing was conducted on the subject iNSitu Lateralized Liner and iNSitu Femoral Stem w/TPS coating to evaluate the device and to demonstrate substantial equivalence. A dimensional analysis was performed for the subject Lateralized Liners to demonstrate the liner thicknesses were not worst-case when compared to the predicate device (neutral liners K161184). Range of motion analysis was performed in accordance with ISO 21535 for the subject Lateralized Liners. Tests related to the porous structure characterization (physical, chemical, and mechanical) of the coating applied to the subject iNSitu Femoral Stems w/TPS are in Master File MAF 628 (owned by APS Materials).

Conclusions

The subject Lateralized Liners and iNSitu Femoral Stems w/TPS have the same indications for use as predicate hip systems. A comparison of technological characteristics and performance testing demonstrates that iNSitu Total Hip System and iNSitu Bipolar System is substantially equivalent to the predicate systems.