May 8, 2025

NextStep Arthropedix
Garrett Spurgeon
VP - Compliance, Regulatory, & Strategy
1800 Triplett Blvd
Akron, Ohio 44720

Re: K242410
Trade/Device Name: NextStep Arthropedix Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: April 11, 2025
Received: April 11, 2025

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,

Lixin Liu -S

Lixin Liu, 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.

Submission Number *(if known)*

K242410

Device Name

NextStep Arthropedix Total Knee System

Indications for Use *(Describe)*

The NextStep Arthropedix Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities.

The NextStep Arthropedix Total Knee System may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The NextStep Arthropedix Total Knee System is designed for cemented use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

The following 510(k) Summary is provided in accordance with 21 CFR 807.92, and prepared on May 8, 2025.

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 26, 2024
Establishment Registration Number:	3002498892

510(k) Contact

Contact:	Garrett Spurgeon
Address:	1800 Triplett Blvd Akron, OH 44321
Phone Number:	(330) 733-7600
Fax Number:	(330) 733-7602
Contact Person:	Garrett Spurgeon

Device Name and Classification

Device Trade Name:	NextStep Arthropedix Total Knee System
Device Common Name:	Total Knee Replacement
Regulation Number and Description:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer, semi- constrained cemented prosthesis.
Device Class:	Class II
Product Codes:	JWH, OIY
Advisory Panel:	87 (Orthopedic)

Legally Marketed Predicate

NextStep Arthropedix is utilizing the Progressive Orthopedic Total Knee System as the predicate device (K142649). Reference devices include the Progressive Orthopedic Total Knee System (K150783), Medacta SPHERE (K121416), the Medacta SPHERE CR with Tibial Stems (K202022), and the Persona Personalized Knee System (K221479).

Device Description

The subject device submission includes a combination of devices based on previously cleared devices (K142649 and K150783) and devices with new designs. This submission will include several identical devices reviewed in K142649 and K150783, new devices not yet reviewed by FDA, and new cleaning, packaging, and sterilization validations for all implants. The subject device submission includes 2 system options for total knee replacement:

• Option 1 – Posterior Stabilized (PS), Cruciate Retaining (CR), and Ultra Congruent Cruciate Retaining (UC-CR) patellofemorotibial total knee replacement system that is based on the Progressive Orthopedic Total Knee System cleared in K142694 and K150783

-Includes additional femoral component sizes, additional vitamin E UHMWPE material option for the symmetrical tibial inserts, and manufacturing patellar components from vitamin E UHMWPE only.

• Option 2 – Medial Pivot Total Knee System, including cruciate retaining (MP-CR) and cruciate substituting (MP-CS) tibiofemoral articulation

Intended Use / Indications for Use

The NextStep Arthropedix Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities.

The NextStep Arthropedix Total Knee System may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The NextStep Arthropedix Total Knee System is designed for cemented use only.

Intended Use Comparison

While there are subtle differences in word choice for the indications associated with the subject and predicate device, the overall indications are the same.

Technological Comparison

The femoral components of the subject and predicate devices are manufactured from identical CoCr alloy (ASTMF75). The tibial bases of the subject and predicate devices are manufactured from identical Ti-6Al-4V alloy (ASTM F136). The tibial inserts of the subject device are manufactured from cross-linked ultra-high molecular weight polyethylene (UHMWPE) that is the same as the predicate device, or vitamin-E blended cross-linked UHMWPE that conforms to ASTM F648. The subject patellar components are also manufactured from the same vitamin-E blended cross-linked UHMWPE. The tibial inserts and patellar components of the reference device (K202022) are manufactured from a similar vitamin E blended UHMWPE. The subject and predicate devices utilize similar principles of operation and are offered in similar size ranges. The subject device differs from the predicate device with additional CR/PS femoral component sizes, additional Vitamin E cross-linked UHWMPE material option

for the symmetric CR/PS/UC-CR tibial inserts, different UHMWPE material option for the patellar components, and the new MP total knee system option.

Non-Clinical and/or Clinical Tests Summary

NextStep Arthropedix performed verification testing to evaluate the mechanical properties of the subject devices and compared to values in consensus standards, published literature, and side-by-side predicate test results. All acceptance criteria were met:

- Fatigue performance of the tibial tray
- Interlock mechanism strength of the tibial tray and insert
- Shear fatigue strength of the tibial insert post
- Tibiofemoral contact area and stress
- Tibiofemoral constraint
- Patellofemoral constraint
- Range of motion
- Wear Testing

Clinical data were not provided and not necessary to support the substantial equivalence of subject device with the predicate device.

Conclusions

The nonclinical performance testing results demonstrate substantial equivalence of the subject NextStep Arthropedix Total Knee System to the legally marketed predicate device.