May 15, 2025

MicroPort Orthopedics, Inc.
Hunter Williams
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K250444
Trade/Device Name: NEXUS® Hip 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: LZO, MEH
Dated: February 12, 2025
Received: February 14, 2025

Dear Hunter Williams:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250444

Device Name

NEXUS® Hip Stem

Indications for Use *(Describe)*

NEXUS® Hip stems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Titanium plasma spray and HA coatings applied to implant surfaces are intended for uncemented arthroplasty.

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) #:

510(k) Summary

Prepared on: 2025-04-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MicroPort Orthopedics, Inc.
Applicant Address	5677 Airline Road Arlington TN 38002 United States
Applicant Contact Telephone	901-451-6511
Applicant Contact	Mr. Hunter Williams
Applicant Contact Email	hunter.williams@ortho.microport.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NEXUS® Hip Stem
Common Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Classification Name	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Regulation Number	888.3353
Product Code(s)	LZO, MEH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200007	PROFEMUR Gladiator Thin HA Classic Hip Stem with Collar	LZO
K150302	PROFEMUR Preserve Classic Stem	LZO
K150862	DePuy Actis DuoFix Hip Prosthesis	MEH
K160907	DePuy Actis DuoFix Hip Prosthesis	MEH
K191632	PROFEMUR TL2 Stems	LZO

Device Description Summary

21 CFR 807.92(a)(4)

The MicroPort NEXUS® Hip Stem is manufactured from titanium alloy (Ti6Al4V per ASTM F620) and includes titanium plasma sprayed coating conforming to ASTM F1580 and a hydroxyapatite (HA) coating conforming to ASTM F1185. The proximal body of the hip stem has a dual titanium and HA plasma spray coating while the distal portion of the hip stem has an HA coating. The NEXUS Hip Stem features collared and collarless options and sizes 0 through 12 with standard and high offsets. The NEXUS Hip Stem is provided sterile and is a single use device. The subject NEXUS Stems are compatible with previously cleared MicroPort femoral head and shell/liner components.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

NEXUS® Hip stems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Titanium plasma spray and HA coatings applied to implant surfaces are intended for uncemented arthroplasty.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same for the subject and primary predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device shares the same material and chemical composition as the primary predicate device, with the same principle of operation. The subject device has the same shape, size range, collar variants, neck lengths and offsets with the same femoral head connection as some or all of the predicate devices and is therefore substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

- Range of Motion (ROM) Analysis per ISO 21535:2023 + A1:2016
- Proximal Fatigue per ISO 7206-6
- Distal Fatigue per ISO 7206-4.
- Impingement Performance Analysis per ASTM F2582-20
- Magnetic Resonance Testing and Analysis per ASTM F2182-19 and FDA Guidance for "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices" issued March 2016, ASTM F2052-21, ASTM F2119-07 (reapproved 2013).

Not Applicable. Clinical data were not necessary for this device.

Each test met the applicable acceptance criteria and the NEXUS Stem was found to be substantially equivalent to its predicate devices. The NEXUS Stem is therefore is expected to be safe, effective and perform as well or superior to its predicates.