March 28, 2025

Smith & Nephew Inc.
Chelsea Bagley
Sr. Regulatory Affairs Specialist
1450 Brooks Rd.
Memphis, Tennessee 38116

Re: K250571
Trade/Device Name: CATALYSTEM Femoral Stems
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, LPH
Dated: February 25, 2025
Received: February 26, 2025

Dear Chelsea Bagley:

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,

RYAN TROMBETTA -S

For: 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)*

K250571

Device Name

CATALYSTEM Femoral Stems

Indications for Use *(Describe)*

The CATALYSTEM Femoral Stems are intended for total and partial hip arthroplasty in skeletally mature patients for the following indications:

Hip components are indicated for individuals undergoing primary surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of degenerative joint disease or any of its composite diagnoses of osteoarthritis, avascular necrosis, and traumatic arthritis.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, congenital dysplasia, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques, and fracture-dislocation of the hip.

The CATALYSTEM Femoral Stems are intended for use without bone cement.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K250571

510(k) Summary

Prepared on: 2025-03-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew Inc.
Applicant Address	1450 Brooks Rd. Memphis TN 38116 United States
Applicant Contact Telephone	(470) 505-8820
Applicant Contact	Mrs. Chelsea Bagley
Applicant Contact Email	chelsea.bagley@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CATALYSTEM Femoral Stems
Common Name	Femoral Stem
Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number	888.3353
Product Code(s)	LZO, MEH, LPH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K240381	CATALYSTEM Femoral Stems	LZO
K052792	ANTHOLOGY Hip Stem	JDI

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this Special 510(k) is to notify the FDA of Smith & Nephew's intent to market the CATALYSTEM Femoral Stems with additional femoral head compatibility. The CATALYSTEM Femoral Stems were previously cleared by the FDA under K240381.

The CATALYSTEM Femoral Stems consists of femoral stem implants intended for primary hip arthroplasty in skeletally mature patients. The CATALYSTEM Femoral Stems are provided sterile to the user via gamma irradiation.

The subject CATALYSTEM Femoral Stems are comprised of two variants: CATALYSTEM Collared and CATALYSTEM Collarless. Both variants are available in standard and high neck offset options.

The CATALYSTEM Femoral Stems are intended to be used with Smith & Nephew femoral heads and acetabular components for total hip arthroplasty and hip hemiarthroplasty.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CATALYSTEM Femoral Stems are intended for total and partial hip arthroplasty in skeletally mature patients for the following indications:

Hip components are indicated for individuals undergoing primary surgery where other treatments or devices have failed in

rehabilitating hips damaged as a result of degenerative joint disease or any of its composite diagnoses of osteoarthritis, avascular necrosis, and traumatic arthritis.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, congenital dysplasia, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques, and fracture-dislocation of the hip.

The CATALYSTEM Femoral Stems are intended for use without bone cement.

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

The indications for use of the subject device are identical to the indications for use of the Primary Predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The overall technological characteristics including device design, function, materials, intended use and indications for use for the CATALYSTEM Femoral Stems are identical to the primary predicate CATALYSTEM Femoral Stems cleared under the premarket notification listed above. The only difference in technological characteristic is the additional femoral head compatibility.

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

Bench Testing
- Neck Fatigue Testing per ISO 7206-6
- Engineering analysis for Distal Stem Fatigue (ISO 7206-4:2010)
- Engineering analysis for Range of Motion (ROM) (ISO 21535:2023)
- Engineering analysis for Impingement (ASTM F2582-20)

No clinical tests were performed to support safety and efficacy of the subject device.

The performance of the bench test was used as a basis for the determination of substantial equivalence. The results of equivalence testing demonstrate acceptable outcomes. The results of the test shows that when compared to the predicate devices the subject device has met the required acceptance criteria and there are no additional risks.