March 13, 2024

Smith & Nephew, Inc.
Anne Remington
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K233949
Trade/Device Name: ACCORD Cable System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS
Dated: December 14, 2023
Received: December 14, 2023

Dear Anne Remington:

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.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K233949

Device Name

ACCORD Cable System

Indications for Use *(Describe)*

The Smith & Nephew ACCORD Cable System is indicated for use in general orthopaedic repair procedures including general cerclage of the femur, trochanteric reattachment, fixation of fractures in conjunction with intramedullary prosthesis (i.e., femoral stem) and screw fixation techniques.

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

Prepared on: 2024-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Smith & Nephew, Inc.
Applicant Address	1450 Brooks Road Memphis TN 38116 United States
Applicant Contact Telephone	7043979060
Applicant Contact	Mrs. Anne Remington
Applicant Contact Email	Anne.Remington@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ACCORD Cable System
Common Name	Bone fixation cerclage
Classification Name	Cerclage, Fixation
Regulation Number	888.3010
Product Code	JDQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223762	Smith & Nephew ACCORD Cable System	JDQ
K031162	Smith & Nephew Orthopaedic Cabling System	JDQ
K993106	Smith & Nephew Bone Plate System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this Traditional 510(k) is to notify the FDA of Smith & Nephew's intent to request clearance for labeling updates, which include indication updates in the IFU/Package Insert, to Smith & Nephew's ACCORD Cable System. There is no significant change in design, technological characteristics, function, sterilization or packaging of the devices as a result of this submission.

The ACCORD Cable System includes cables (with or without clamps), trochanteric grips, and plates. (K223762).

The subject Smith & Nephew ACCORD Cable System devices are identical in function, design features, materials, sterilization, packaging, manufacturing methods and operational principles to what was previously 510(k) cleared (K223762, K031162, K993106). These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

The ACCORD Cable System is intended for use in long bone fracture fixation and general cerclage in adult skeletally mature patients.

The Smith & Nephew ACCORD Cable System consists of Cobalt Chrome cables (without clamps) to be used with the ACCORD Titanium trochanteric grips or ACCORD Titanium plates and also Stainless Steel and Cobalt Chrome cables with clamps to be used alone. These materials are identical to the material that has been previously cleared in K223762, K031162, and K993106.

The implants within this system are single-use and are Gamma sterilized.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Smith & Nephew ACCORD Cable System is indicated for use in general orthopaedic repair procedures including general cerclage of the femur, trochanteric reattachment, fixation of fractures in conjunction with intramedullary prosthesis (i.e., femoral stem) and screw fixation techniques.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The purpose of this Traditional 510(k) is to notify the FDA of our intent to request clearance for changes to Smith & Nephew's ACCORD Cable System labeling, including updated indications.

The main change described in this 510(k) is removal of indications that were not previously used or are not applicable to the subject devices from the Instructions for Use (K223762) to meet EU MDR requirements.

The Smith & Nephew ACCORD Cable System is identical in function, design features,
materials, sterilization, packaging, manufacturing methods and operational principles to the commercially available predicate devices Smith & Nephew ACCORD Cable System (K223762), Smith & Nephew Orthopaedic Cabling System (K031162), and Smith & Nephew Bone Plate System (K993106).

Technological Comparison

21 CFR 807.92(a)(6)

The overall technological characteristic including device design and material of the subject devices are identical to the predicates cleared under the premarket notifications Smith & Nephew ACCORD Cable System (K223762), Smith & Nephew Orthopaedic Cabling System (K031162), and Smith & Nephew Bone Plate System (K993106). As a result, all relevant testing makes references to existing information previously provided to the agency.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The purpose of this traditional 510(k) is to request clearance from FDA for labeling changes to the subject Smith & Nephew ACCORD System implants.

The subject Smith & Nephew ACCORD Cable System devices are identical in function, design features, materials, packaging, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared (K223762, K031162, K993106). These labeling updates do not affect the safety and effectiveness of the subject devices when used as labeled.

Therefore, since there are no changes to the design features, materials, or manufacturing methods of the subject ACCORD Cable System devices, no performance testing (bench, animal, clinical) was required.

Not Applicable.

No modifications are being introduced to the subject devices as a result of this filing. The subject devices are substantially equivalent to the previously 510(k) cleared predicate devices (K223762, K031162, K993106).