May 30, 2023

Smith & Nephew, Inc.
Rose Beifuss
Senior Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K223762
Trade/Device Name: Smith & Nephew ACCORD™ Cable System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, JDQ
Dated: April 27, 2023
Received: April 27, 2023

Dear Rose Beifuss:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223762

Device Name
Smith & Nephew ACCORD™ Cable System

Indications for Use *(Describe)*
The Smith & Nephew Cabling System of the Smith & Nephew ACCORD™ Cable System is indicated for general orthopaedic repair procedures including patellar fractures, general cerclage, trochanteric reattachment, femoral and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nail and screw fixation techniques.
Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below.
• Primary total hip arthroplasty.

• Revision total hip arthroplasty.

• Any procedure using anterolateral or lateral approaches.

The ACCORD™ Titanium Plates of the Smith & Nephew ACCORD™ Cable System are indicated for adult or pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

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

Submitted by:	Smith & Nephew, Inc. Orthopedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Submission:	May 25, 2023
Contact Person:	Rose Beifuss Senior Manager, Regulatory Affairs Rose.Beifuss@smith-nephew.com Mobile: (385)253-2551 Jessica Roach Regulatory Affairs Specialist II Jessica.Roach@smith-nephew.com Mobile: (713)855-1291
Name of Device:	Smith & Nephew ACCORD™ Cable System
Common Name:	Bone Plates, Cabling System
Device Classification Name and Reference:	21 CFR 888.3030 – Single/Multiple Component Metallic Bone Fixation Appliances and Accessories 21 CFR 888.3010 – Bone Fixation Cerclage
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Codes:	HRS, JDQ
Predicate Devices:	• Smith & Nephew Bone Plate System (Bone Plates, Bone Screws and Accessories) (K993106 S.E. 12/09/1999) • Smith & Nephew Orthopaedic Cabling SystemK031162 (S.E. 05/01/2003)

Device Description

The purpose of this Traditional 510(k) is to add MR safety information to the labeling and update the information within the labeling, including the package insert for the subject Smith & Nephew ACCORD™ Cable System. The technological characteristics, function of the devices, packaging and sterilization remain unchanged. No modifications have been made to the materials, sterilization, or the manufacturing processes of the previously cleared devices due tothe addition of MR labeling for this subject 510(k). The Smith & Nephew ACCORD™ Cable System consists of the following previously cleared devices:

- The ACCORD™ Titanium Plates: Bone plates of various sizes to accommodate the individual requirements of patient anatomy, cleared under K993106.

- The Smith & Nephew Cabling System: Cables with or without clamps and trochanteric grips, cleared under K031162.

Indications for Use

The Smith & Nephew Cabling System of the Smith & Nephew ACCORD™ Cable System is indicated for general orthopaedic repair procedures including patellar fractures, general cerclage, trochanteric reattachment, femoral and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nail and screw fixation techniques.

Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below:

- Primary total hip arthroplasty.
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condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

Technological Characteristics

The material of the subject devices is the same as the predicate Smith & Nephew components cleared under the premarket notifications listed in **Table 5.1**. The designs of the subject devices are equivalent to those of the predicate Smith & Nephew components cleared under the premarket notifications listed in **Table 5.1**.

Performance Data

Magnetic Resonance Imaging (MRI) compatibility testing was conducted as per the FDA's Guidance and the Standards listed below:

1. ASTM F2052-15 Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.
2. ASTM F2182-19e2, "Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging"
3. FDA Guidance Document: "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment: Guidance for Industry and Food and Drug Administration Staff", 20May2021.
4. Reporting of Computational Modeling in Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff, September 21, 2016
5. IEC 60601-2-33 (Ed 3.2), "Medical electrical equipment -Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis" (2015).
6. ISO/TS 10974:2018(E) "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.

MR safety testing/assessments support the appropriate MR parameters and symbols found in the subject device labeling.

Engineering analysis and dynamic tensile strength testing demonstrated substantially equivalent mechanical performance of the plates and cables, respectively.

Substantial Equivalence Information

The subject components are identical in function, materials, sterilization, manufacturing methods and operational principles to the commercially available predicate devices listed in **Table 5.1** below.

Table 5.1: Substantially Equivalent Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Bone Plate System	K993106	12/09/1999
Smith & Nephew, Inc.	Orthopaedic Cabling System	K031162	05/01/2003

Conclusion

In summary, the Smith & Nephew ACCORD™ Cable System is identical in function, materials, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared and do not affect the safety and effectiveness of the subject devices when used as labeled. Due to the supporting documentation within this filing, it is concluded that the subject devices are substantially equivalent to the predicate devices.