December 21, 2023

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

Re: K233396
Trade/Device Name: Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 29, 2023
Received: October 3, 2023

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.

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
DHT6B: 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)*
K233396

Device Name
Cannulated Screw System

Indications for Use *(Describe)*
The 4.0 mm Cannulated Screws and associated washers are indicated for arthrodesis and osteotomies of small bones and small joints, and ankle fracture.

The 5.5 mm, 6.5 mm, 7.0 mm, and 8.0 mm Cannulated Screws, Cannulated Hip Pins and associated washers are indicated for fracture fixation, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device.

The Smith & Nephew 2.5 mm, 3.0 mm Cannulated and 3.0 mm Headless Compression Screws are indicated for fixation of fractures, bunionectomies and osteotomies of small bones, and arthrodesis of small joints.

The Smith & Nephew 2.0 mm QFX Screw is indicated for osteotomies of the lesser metatarsals, and osteotomies and fractures of the phalanges.

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.

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510(k) Summary

Prepared on: 2023-12-20

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	4705058820
Applicant Contact	Mrs. Chelsea Bagley
Applicant Contact Email	chelsea.bagley@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cannulated Screw System
Common Name	Screw, Fixation, Bone
Classification Name	- Smooth or threaded metallic bone fixation fastener (primary) - Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	888.3040 (primary), 888.3030
Product Code	HWC (primary), HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K090675	Smith & Nephew, Inc. VLP Foot Plating, Screw System and Acce	HWC
K111994	Smith & Nephew Cannulated Screws and Washers	HWC
K213126	Smith & Nephew, Inc. Plates and Screws Systems	HWC

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 Cannulated Screw System. There is no significant change in design, technological characteristics, function, sterilization or packaging of the devices as a result of this submission.

The subject Cannulated Screw System includes the 2.0 QFX Screw, 2.5mm and 3.0mm Cannulated Screws, 3.0mm Headless Compression Screws, 4.0mm, 5.5mm, 6.5mm, 7.0mm, and 8.0mm Cannulated Screws and associated Washers (K090675, K111994, K213126).

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

The Cannulated Screw System is intended for reconstruction, arthrodesis, and osteotomies of various bones and bone fragments appropriate for the size of the device.

The Smith & Nephew Cannulated Screw System consists of stainless steel (316L conforming to ASTM F138, ASTM F139 and ISO 5832-1 or titanium (Ti-6Al-4V conforming to ASTM F1472/ISO 5832-3) implantable devices of many styles for use in fracture fixation. These

materials are identical to the material that has been previously cleared in K090675, K111994 and K213126. The Smith & Nephew Cannulated Screws product family includes Large Cannulated Screws, Small Cannulated Screws, Cannulated Hip Pins, Hip Screws, QFX Screws, and associated Washers. The components are available in various diameters, thread options, and lengths. All screws are designed with a self-drilling, self-tapping tip to facilitate easy implantation in combination with a reverse cutting flute design to assist with implant removal. Select screws are designed with low-profile screw heads for reduced soft tissue irritation, and 3.0mm and 7.0mm screws are available headless.

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

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The 4.0 mm Cannulated Screws and associated washers are indicated for arthrodesis and osteotomies of small bones and small joints, and ankle fracture.

The 5.5 mm, 6.5 mm, 7.0 mm, and 8.0 mm Cannulated Screws, Cannulated Hip Pins and associated washers are indicated for fracture fixation, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device.

The Smith & Nephew 2.5 mm, 3.0 mm Cannulated and 3.0 mm Headless Compression Screws are indicated for fixation of fractures, bunionectomies and osteotomies of small bones, and arthrodesis of small joints.

The Smith & Nephew 2.0 mm QFX Screw is indicated for osteotomies of the lesser metatarsals, and osteotomies and fractures of the phalanges.

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 Cannulated Screw System labeling, including updated indications.

The main change described in this 510(k) is an indication verbiage change for the 4.0mm Cannulated Screws which is being made for user clarification. The indications were updated to remove the list of various bones since they were examples and not an exhaustive list. The indications were also updated to add in 'ankle fracture' for user clarification as the previous indications included examples of bones of the ankle but did not include all possible bones where the devices would be used since it was not an exhaustive list. Additionally, across all variants of the Cannulated Screw System, indications that were not previously used or are not applicable to the subject devices were also removed from the Instructions for Use.

The Smith & Nephew Cannulated Screw System is identical in function, design features,
materials, sterilization, packaging, manufacturing methods and operational principles to the commercially available predicate devices Smith & Nephew, Inc. VLP Foot Plating, Screw System and Accessories (K090675, 06/04/2009), Smith & Nephew Cannulated Screws and Washers (K111994, 10/11/2011) and Smith & Nephew, Inc. Plates and Screws Systems (K213126, 09/29/2022).

Technological Comparison

21 CFR 807.92(a)(6)

The overall technological characteristics including device design and material of the subject devices are the same as the predicates cleared under the premarket notifications Smith & Nephew, Inc. VLP Foot Plating, Screw System and Accessories (K090675, 06/04/2009), Smith & Nephew Cannulated Screws and Washers (K111994, 10/11/2011) and Smith & Nephew, Inc. Plates and Screws Systems (K213126, 09/29/2022).
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 Cannulated Screw System implants.

The subject Smith & Nephew Cannulated Screw System devices are identical in function, design features, materials, packaging, sterilization, manufacturing methods and operational principles to what was previously 510(k) cleared. 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 Cannulated Screw 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.