April 2, 2021

Smith & Nephew, Inc.
Thomas Fearnley
Senior Regulatory Affairs Specialist
1450 E Brooks Rd
Memphis, Tennessee 38116

Re: K210784
Trade/Device Name: Extended HA Half Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW
Dated: March 15, 2021
Received: March 16, 2021

Dear Thomas Fearnley:

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,

Ting Song, Ph.D., R.A.C.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210784

Device Name
Extended HA Half Pins

Indications for Use *(Describe)*
The Extended HA Half Pins are intended to be used with an external fixation system for fixation of fractures of long bones, joint fusions, and limb lengthening or deformity corrections that involve cutting of the bone and temporary stabilization for the indications listed below.

1. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
2. Open and closed fracture fixation
3. Pseudarthrosis of long bones
4. Limb lengthening by distraction
5. Correction of bony or soft tissue deformities
6. Joint arthrodesis
7. Infected fractures
8. Nonunions

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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	March 13, 2021
	Thomas Fearnley Senior Regulatory Affairs Specialist T 901-399-1224 F 901-566-7022
Name of Device:	Extended HA Half Pins
Common Name:	Pin, Fixation, Threaded
Device Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JDW

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	**Jet-X HA Coated Half Pins (primary predicate)**	**K023921**	**February 5, 2003**
Smith & Nephew, Inc.	Modification to Jet-X HA Coated Half Pins	K033289	January 13, 2004

Device Description

Subject of this premarket notification is the Extended HA Half Pins. The proposed devices are design modifications of the Jet-X HA Coated Half Pins to extend the HA coating to the shank of the Half Pins.

Indications for Use

The Extended HA Half Pins are intended to be used with an external fixation system for fixation of fractures of long bones, joint fusions, and limb lengthening or deformity corrections that involve cutting of the bone and temporary stabilization for the indications listed below.

1. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
2. Open and closed fracture fixation
3. Pseudarthrosis of long bones
4. Limb lengthening by distraction
5. Correction of bony or soft tissue deformities
6. Joint arthrodesis

7. Infected fractures
8. Nonunions

Technological Characteristics

Device comparisons described in this premarket notification demonstrated that the proposed devices are substantially equivalent to legally marketed predicates with respect to intended use, indications, and performance characteristics.

Summary of Pre-Clinical Testing

- Testing as required per FDA Guidance 510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants has been completed and is included in the supplier Masterfile.

Conclusion

This Special 510(k) premarket notification is being submitted to request clearance for the Extended HA Half Pins. Based on similarities to the predicate Jet-X HA Coated Half Pins, the subject devices are substantially equivalent to the predicate devices.