



July 29, 2021

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

Re: K210953

Trade/Device Name: SMART Taylor Spatial Frame
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: June 29, 2021
Received: June 30, 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

Indications for Use

510(k) Number (if known)
K210953

Device Name
SMART Taylor Spatial Frame

Indications for Use (Describe)

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.

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Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
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Date of Summary: July 28, 2021
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Name of Device: SMART Taylor Spatial Frame

Common Name: Multilateral Fixators and Accessories

Device Classification Name and Reference: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Device Class: Class II

Panel Code: Orthopaedics/87

Product Code: KTT, OSN

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew TSF and Circular Fixation System (primary predicate)	K093047	September 27, 2010
Smith & Nephew, Inc.	Smith & Nephew, Inc. Spatialframe.Com V5.0 Web-Based Software	K142520	November 20, 2014
Smith & Nephew, Inc.	Smith & Nephew External Fixation System – Unilateral (Linear) & Multilateral (Circular) Fixators and Accessories	K994143	February 18, 2000
Smith & Nephew, Inc.	Taylor Spatial Frame External Fixation System	K970748	May 9, 1997

Device Description

Subject of this premarket notification is the SMART Taylor Spatial Frame. The proposed devices incorporate design features similar to those currently incorporated on previously cleared Smith & Nephew multilateral external fixation systems. The SMART Taylor Spatial Frame consists of full or partial rings, telescoping struts other fixation accessories made from aluminum and stainless steel materials. The system also includes a web-based software component designed for use in assisting physicians creating fixator adjustment schedules and mobile app.

Indications for Use

The indications for the Smith & Nephew SMART Taylor Spatial Frame are the following:

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

- Construct and frame component testing were completed per ASTM F1541 “Standard Specification and Test Methods for External Skeletal Fixation Devices”
- Magnetic resonance imaging (MRI) compatibility testing was conducted as per the FDA’s guidance “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment”, December 11, 2014.
- Software Verification and Validation per FDA guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” dated May 11, 2005 and “General Principles of Software Validation” dated January 11, 2002.

Conclusion

This Traditional 510(k) premarket notification is being submitted to request clearance for the SMART Taylor Spatial Frame. Based on similarities to the predicate multilateral external fixation systems and a review of the mechanical and software testing performed, the subject devices are substantially equivalent to the predicate devices.