August 25, 2022

Smith & Nephew, Inc.
Amanda Lammey
Regulatory Affairs Specialist I
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K221792
Trade/Device Name: Acute QC Strut and Components
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, JDW
Dated: June 17, 2022
Received: June 21, 2022

Dear Amanda Lammey:

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 and Part 809); 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,

For: 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)*
K221792

Device Name
Acute QC Strut and Components

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K221792

Acute QC Strut and Components

510(k) Summary Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	June 18, 2022
Primary Contact Person:	Amanda Lammey, Regulatory Affairs Specialist I M 901-833-1364 H 901-386-3453
Secondary Contact Person:	Brad Sheals, Senior Manager Regulatory Affairs M 901-288-7141 W 901-399-6897
Name of Device:	Acute QC Strut and Components
Common Name:	External Fixation Systems
Device Classification Name and Reference:	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class II
Panel Code:	Orthopedics/87
Product Code:	KTT, OSN, JDW
Predicate Device:	Primary Predicate – K210953 – SMART Taylor Spatial Frame (S.E. 07/29/2021) Secondary Predicate – K994143 – ILIZAROV™ External Fixation System (S.E. 02/18/2000)

Device Description

The purpose of this Special 510(k) is to notify FDA of our intent to market the subject Smith & Nephew Acute QC Struts. The Smith & Nephew Acute QC Strut and Components consist of multiple sized struts (e.g., X Short, Short, Medium, and Long) and components such as nuts, bands, and washers to build an external fixation construct.

Subject of this premarket notification is the Acute QC Strut and Components. The Smith & Nephew Acute QC Strut and Components consist of multiple sized struts (e.g., X Short, Short, Medium, and Long) and components such as nuts, bands, and washers to build an external fixation construct. The proposed devices incorporate design features similar to those currently incorporated in previously cleared Smith & Nephew SMART Taylor Spatial Frame and ILIZAROV™ External Fixation System. The Acute QC Strut and Components will be manufactured from aluminum, composite, and stainless-steel material, which is identical to that of the predicate devices of the SMART Taylor Spatial Frame System (e.g., K210953, S.E. 07/29/2021).

The Smith & Nephew Acute QC Strut and Components are line additions to the predicate, SMART Taylor Spatial Frame System, which allows for acute multi-planer angular corrections to bone alignment due to a trauma event. The subject Acute QC Strut and Components and the predicate SMART Taylor Spatial Frame are identical in intended use and indications for use. The subject Acute QC Strut and Components are identical in indications for use also to the predicate ILIZAROV™ External Fixation System except for two statements: post-traumatic joint contracture which has resulted in loss of range of motion and management of comminuted intra-articular fractures of the distal radius. Both predicates are used in this submission because the subject Acute QC Strut and Components are line additions to the SMART Taylor Spatial Frame System which is based on the ILIZAROV™ Method. Therefore, the SMART Taylor Spatial

Frame System is the primary predicate and the ILIZAROV™ External Fixation System is the secondary predicate. The subject Acute QC Strut and Components: Acute QC Strut X Short, Acute QC Strut Short, Acute QC Strut Medium, Acute QC Strut Long, and Acute QC Strut Band are substantially equivalent to the cleared SMART Taylor Spatial Frame devices cleared via premarket notification K210953 (S.E. 07/29/2021). The subject Acute QC Strut and Components: Speed Nut, Half Pin Washer 2MM, and the Half Pin Washer 4MM are substantially equivalent to the previously cleared ILIZAROV™ External Fixation System devices: NUT, FIXATION BOLT WASHER 2MM and the FIXATION BOLT WASHER 4MM cleared via premarket notification K994143 (S.E. 02/18/2000).

Intended Use

External fixation devices are used on adults or pediatric patients as required. External fixation systems consist of various components that are used to build fixator assemblies unique to the patient's needs. These devices are modular; therefore, a multitude of different fixator frame configurations are possible. External fixation devices are used for the following indications below.

Indications for Use

The indications for the Smith & Nephew Acute QC Strut and Components 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

These indications are identical to the indications of the subject devices and the primary predicate devices of the SMART Taylor Spatial Frame System (e.g., K210953, S.E. 07/29/2021). All of the subject devices, primary predicate devices, and secondary predicate devices are intended for single use.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the subject devices, Acute QC Strut and Components, are substantially equivalent to legally marketed predicates with respect to intended use, indications for use, similar design, and performance characteristics. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Design Changes

The overall kinematics, intended use, material, and manufacturing process of the new device mimics those of the predicate devices. Design modifications have been introduced which provided a lock multiplanar mechanism to provide surgeons the ability to quickly build a circular frame to correct multiplanar deformities and fractures in trauma settings. The subject Acute QC Struts removed the universal joints that the primary predicate, SMART Taylor Spatial Frame (e.g., K210953, S.E. 07/29/2021), uses and replaced it with a ball joint. The subject Acute QC Strut Band removed the laseretch number from the predicate SMART FX ID Band (K210953) which was only used when utilizing the program software from the predicate SMART Taylor Spatial Frame System. The software is not used for the subject Acute QC Strut Band. The

subject Speed Nut modified the predicate, ILIZAROV™ External Fixation System (e.g., K994143 S.E. 01/18/2000), nut by adding knurled sections to the nut. The modifications were made by adding knurled sections to the nut to provide the ability to advance the nut without the use of instruments such as a wrench. The subject Half Pin Washers modified the predicate WASHER FIX BOLTS (K994143) by adding raised posts to provide additional stability to the 3-sided half pins. The intended use of the subject devices did not change from the predicate devices. For detailed technology changes and visualizations of the subject and predicate devices, see **Section 12** of this submission.

Substantial Equivalence

The overall design, materials, and indications for use for the Acute QC Strut and Components are substantially equivalent to the predicate devices listed in the **Table 6.1** below.

Table 6.1: Substantially Equivalent Predicate Devices

	Manufacturer	Description	Submission Number	Pro Code	Clearance Date
Primary Predicate	Smith & Nephew, Inc.	SMART Taylor Spatial Frame	K210953	KTT, OSN	July 29, 2021
Secondary Predicate	Smith & Nephew, Inc.	ILIZAROV™ External Fixation System	K994143	JDW	February 18, 2000

Performance Testing:

To further support a determination of substantial equivalence, performance testing was conducted on the subject, implantable devices in comparison against one or more of the previously cleared predicate devices described in **Table 6.1** above. A review

of the mechanical data in the submission indicates that the Acute QC Strut and Components are substantially equivalent to the previously cleared predicate devices. The following characteristics and performance testing were reviewed to determine the substantial equivalence.

- Fully Reversed Compressive Fatigue Loading of the Construct
- Continuous Compressive Static Loading of the Construct
- Static Compressive Bending Load on the Ball Joint Assembly
- Compressive Fatigue Loading of the Ball Joint Assembly
- Torsional Strength Testing of the Subject Half Pin Washer

A rationale was provided for the subject Acute QC Strut and Components which states that the subject devices match the pyrogenicity information of the primary predicate, SMART Taylor Spatial Frame System (e.g., K210953, S.E. 07/29/2021).

A biological risk assessment of the devices was evaluated and completed in compliance with *ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* to assess the risk of harm to health resulting from exposure to the device for the intended duration of contact. The subject Acute QC Struts are classified as surface-contacting devices that contact intact skin for prolonged durations (>24 hr to 30 days). The subject Acute QC Struts were determined to not present a greater biological risk than the cleared worst-case representative SMART FX STRUT (e.g., K210953, S.E. 07/29/2021). The Acute QC Strut Band, Speed Nut, and Half Pin Washers are all nonpatient contacting devices that are not required to have detailed biological endpoint evaluation per ISO 10993-1. All manufacture materials of these devices have long histories of safe use in medical devices.

An MR safety technical memo, which can be found in **Exhibit 9** of this submission, was completed comparing the subject Acute QC Strut to external fixation devices of similar

indications which have been previously evaluated for MRI safety and compatibility. The material and devices associated with the subject Acute QC Strut and Components are the same as the previously evaluated Smith and Nephew, Inc. external fixation system, SMART Taylor Spatial Frame (e.g., K210953, S.E. 07/29/2021). The subject Acute QC Strut is considered at least similar in maximum mass, maximum length, material, surface finish, overall shape, and location/orientation as compared to the corresponding tests in the predicate studies. Thus, the subject Acute QC Strut would be expected to have at least similar responses in consideration of magnetically induced RF heating, magnetically induced displacement force, magnetically induced torque, and the MR image artifact as the previously cleared premarket notification tests determined. This technical memo matches the MR parameters of the cleared primary predicate, SMART Taylor Spatial Frame (e.g., K210953, S.E. 07/29/2021) and the subject Acute QC Strut and Components were determined to be MR Unsafe.

The packaging and labeling, including the instructions for use (**Exhibit 4**) and package insert **(Exhibit 5)** which was previously submitted to the FDA via premarket notification K210953 (S.E. 07/29/2021) for the SMART Taylor Spatial Frame System, also contains the MR Unsafe icons and/or parameters as specified in ASTM F2503, as appropriate.

Conclusion

In summary, this Special 510(k) premarket notification is being submitted to request clearance for the subject Acute QC Strut and Components. Based on similarities to the predicate SMART Taylor Spatial Frame and ILIZAROV™ External Fixation System, the subject line additions introduce no new risks related to the safety and effectiveness of the devices and Smith&Nephew, Inc believes the subject devices are substantially equivalent to the commercially available predicate devices listed in **Table 6.1**.