December 8, 2020

Smith & Nephew, Inc.
Brad Sheals
Senior Regulatory Affairs Manager
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K201253
Trade/Device Name: Modular Rail System, TAYLOR SPATIAL FRAME External Fixator, JET-X Fixator, ILIZAROV External Fixator, Other External Fixation
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, LXT, JDW, OSN
Dated: November 6, 2020
Received: November 10, 2020

Dear Brad Sheals:

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,

for Ting Song, PhD
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
List of cleared devices in K201253

List of Cleared Devices in K201253

1. Smith & Nephew Rail System – MR Unsafe
2. Taylor Spatial Frame External Fixator – MR Conditional (only when used with Frame Stabilizer Tool)
3. JET-X Fixator – MR Conditional
4. ILIZAROV External Fixator – MR Unsafe

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201253

Device Name
ILIZAROV SYSTEM

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 (not applicable for use with COMPASS Universal Hinge)
5. Correction of bony or soft tissue deformities (not applicable for use with COMPASS Universal Hinge)
6. Joint arthrodesis (not applicable for use with COMPASS Universal Hinge)
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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201253

Device Name
JET-X System

Indications for Use *(Describe)*

1. Open and closed fractures fixation
2. Bony or soft tissue deformities
3. Infected fractures
4. Mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201253

Device Name
MODULAR RAIL SYSTEM

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. Infected fractures
7. 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201253

Device Name
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)

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510(k) Summary

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Contact Person:	Mr. Brad Sheals, MS Senior Regulatory Affairs Manager T 901-288-7141
Date Prepared:	November 19, 2020
Name of Device:	Smith & Nephew Modular Rail System, Smith & Nephew Taylor Spatial Frame Fixator, Smith & Nephew JET-X Fixator, Smith & Nephew Other External Fixation, Ilizarov External Fixation System
Common Name:	External Fixators and Accessories
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories. 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	KTT, LXT, JDW, OSN
Predicate Device:	Smith & Nephew Modular Rail System, Smith & Nephew Taylor Spatial Frame Fixator, Smith & Nephew JET-X Fixator, Smith & Nephew Other External Fixation, Ilizarov External Fixation System

The predicate devices have not been subject to a design-related recall.

No reference devices were used in this submission.

Device Description

The primary purpose of this Traditional 510(k) is to add the MR safety information to the labeling for the Smith & Nephew External Fixations Systems. In addition, select product systems within the submission are modifying the indications for use and updating the package insert due to European MDR related updates. The Smith & Nephew External Fixation Systems consist of the TAYLOR SPATIAL FRAME Fixator, ILIZAROV External Fixator, JET-X Fixator and the Smith & Nephew Rail System. In general, each system consists of a unique combination of pins, bars, clamps, rings, struts, rods and/or rails to achieve fixation of a bone or joint. The JET-X system can be used with various clamps, pins, and carbon fiber bars to provide versatility in achieving fixation. The JET-X MINI system utilizes a smaller subset of components from the JET-X system. The MRS

consists of a combination of pins, modular rail segments (linear or arcs), clamps, and distraction/compression device(s) to provide fixation. The TSF assemblies generally utilize 2-3 rings (half ring, 2/3 ring, full ring, and/or foot ring) or plates (U-plate), as well as struts to provide the framework for fixation. A series of rods, pins, and wires are then used to provide stability and fixation to the bone. The ILIZAROV system generally implements thin wire fixation alone or as an adjunct to internal fixation. Like the TSF, the ILIZAROV system contains a frame that consists of a combination of rings and rods, while pins and wires provide fixation of the frame to the bone. As seen in the subject device submission, the device design, technological characteristics, physical properties (e.g. materials), function of the devices, manufacturing processes, packaging and sterilization remain unchanged.

Indications for Use

The indications for the Smith & Nephew External Fixation Systems are the following:

Smith&Nephew Modular Rail System
Indication for Use

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. Infected fractures
7. Nonunions

Smith & Nephew Taylor Spatial Frame Fixator
Indication for Use

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

Smith & Nephew JET-X Fixator
Indication for Use

1. Open and closed fractures fixation
2. Bony or soft tissue deformities
3. Infected fractures
4. Mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius

Smith & Nephew Ilizarov System

Indication for Use

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 (not applicable for use with COMPASS Universal Hinge)
5. Correction of bony or soft tissue deformities (not applicable for use with COMPASS Universal Hinge)
6. Joint arthrodesis (not applicable for use with COMPASS Universal Hinge)
7. Infected fractures
8. Nonunions

Technological Characteristics

There are no technology differences between the subject device and predicate devices as these devices are intended for use as external fixators. The device design and material of the subject device are same as the predicate Smith & Nephew System(s) cleared under the premarket notifications listed in Tables 5.1-5.5.

Performance Data

The following performance data was provided in support of the substantial equivalence determination.

Magnetic resonance Imaging (MRI)

MRI compatibility testing/assessment was conducted as per the FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", December 11, 2014 and the standards listed below:

1. Magnetically induced displacement force (ASTM F2052)
2. Magnetically induced torque (ASTM F2213)
3. Radiofrequency (RF) induced heating (ASTM F2182)
4. MR image artifact (ASTM F2119)

In summary, MR safety testing/assessment supports the appropriate MR parameters and symbols found in the subject device labeling.

Substantial Equivalence Information

The subject Smith & Nephew External Fixation Systems are identical in function, design features, materials, sterilization, manufacturing methods and operational principles to the commercially available predicate devices listed in their respective tables below.

Table 5.1: Substantially Equivalent Predicates to the External Fixation Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew Rail System	K090926 K120871	6/8/2009 6/7/2012

Table 5.2: Substantially Equivalent Predicates to the External Fixation Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	TAYLOR SPATIAL FRAME External Fixator	K023921 K994143 K093047	2/5/2003 2/18/2000 9/27/2010

Table 5.3: Substantially Equivalent Predicates to the External Fixation Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	JET-X Fixator	K023134 K072212 K994143 K042312 K120871	10/9/2002 3/7/2008 2/18/2000 9/24/2004 6/7/2012

Table 5.4: Substantially Equivalent Predicates to the External Fixation Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	ILIZAROV External Fixator/System	K042436 K920024 K953397 K970751 K994143 K970713 K093047 K120871 K130479	10/7/2004 1/27/1992 10/31/1995 4/16/1997 2/18/2000 4/3/1997 9/27/2010 6/7/2012 5/17/2013

Table 5.5: Substantially Equivalent Predicates to the External Fixation Systems

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Other External Fixation	K994143 K120871	2/18/2000 6/7/2012

Conclusions

In summary, the only differences between the subject devices and the commercially available predicate device was supporting MR safety testing/assessment, addition of MR safety information to the labeling, the indications and the information within the package insert were updated due to European MDR related changes. These differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the subject devices. The subject Smith & Nephew External Fixation Systems are identical in function, design features, 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 device(s) are substantially equivalent to the predicate device(s).