December 8, 2022

Smith & Nephew, Inc.
Allison Francis
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K223112
Trade/Device Name: MAVERICK Mini External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: September 30, 2022
Received: October 3, 2022

Dear Allison Francis:

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 -S

Ting Song, Ph.D.
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)*

K223112

Device Name
MAVERICK Mini External Fixation System

Indications for Use *(Describe)*
Smith & Nephew's MAVERICK and MAVERICK Mini External Fixation System is intended to be used for temporary stabilization of the long bones, feet, pelvis, and wrist.

The indications for the Smith & Nephew MAVERICK Mini External Fixation System are the following:
* Open and closed fracture fixation
* Bony or soft tissue deformities

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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Smith+Nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	September 30, 2022
	Primary Contact: Ms. Allison Francis Regulatory Affairs Specialist T 901-572-5959
	Secondary Contact: Mr. Brad Sheals, MS Senior Regulatory Affairs Manager T 901-288-7141 F 901-566-7911
Name of Device:	MAVERICK Mini External Fixation System
Common Name:	Multi-lateral 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, JDW

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	**MAVERICK External Fixation System (Primary Predicate)**	**K213874**	**February 11, 2022**
Smith & Nephew, Inc.	Smith & Nephew External Fixation System (Jet-X)	K994143	February 18, 2000

Device Description

The subject of this premarket notification is the MAVERICK Mini External Fixation System. The system is an external fixation system that consists of various components used in the management of pelvic, feet, wrist, and long bone fractures and reconstructive and corrective orthopedic surgery. The system consists of stainless steel bone pins, composite and titanium bars, and titanium clamps. These components can be combined to build a frame which is appropriate for each specific application.

Indications for Use
Smith & Nephew's MAVERICK and MAVERICK Mini External Fixation System is intended to be used for temporary stabilization of the long bones, feet, pelvis, and wrist.

The indications for the Smith & Nephew MAVERICK Mini External Fixation System are the following:

- Open and closed fracture fixation
- Bony or soft tissue deformities

Technological Characteristics
The principle of operation for the subject and the predicate devices is stabilization of bones through fixation with pins clamped to an external fixation frame built with composite bars. The MAVERICK Mini External Fixation System is similar to legally marketed predicate devices in that they are manufactured from similar materials, are of structurally similar size, strength and stiffness, and incorporate similar methods of assembly and adjustment.

Performance Testing
To further support a determination of substantial equivalence, Mechanical testing and/or assessments were utilized. A review of the data indicates that the subject MAVERICK Mini External Fixation System is substantially equivalent to one or more of the previously cleared predicate devices listed above. The following overall bench performance strategy was used as a basis for the determination of substantial equivalence.

Overall Bench Performance Testing Strategy

Device Testing	
Subject Clamps Testing	Torsional Grip Strength with Pins Axial Grip Strength with Pins Resistance to Slip at Internal Swivel Junction Axial Grip Strength with Bars Torsional Grip Strength of Bars
Rigidity Testing to Failure of Full Constructs	Load to Failure of Wrist Spanning Style Frames – double pin clamps Load to Failure of Wrist Spanning Style Frames – bar to pin clamps
Mating to MAVERICK Large System	Large Clamp Grip on 6mm Bars

A Declaration of Conformity for biocompatibility assessment was completed. A MRI justification was utilized in lieu of testing.

Conclusion
Based on similarities to the predicate multi-lateral external fixation systems and a review of testing performed, the subject MAVERICK Mini External Fixation System is substantially equivalent to the commercially available predicate devices.