



February 11, 2022

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

Re: K213874

Trade/Device Name: MAVERICK 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: December 10, 2021
Received: December 13, 2021

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,

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)

K213874

Device Name

MAVERICK External Fixation System

Indications for Use (Describe)

The MAVERICK External Fixation System is intended to be used for temporary stabilization of the long bones, feet, and pelvis.

The indications for the Smith & Nephew MAVERICK 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.

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Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
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Date of Summary: December 10, 2021
Mr. Brad Sheals, MS
Senior Regulatory Affairs Manager
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Name of Device: MAVERICK 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. | Jet-X Bar System Clamps, Bars and Posts – MR Safe (Primary Predicate) | K072212 | March 7, 2008 |
| Austin Miller Trauma LLC | Austin Miller Large External Fixation System | K181528 | February 28, 2019 |
| 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 External Fixation System. The system is an external fixation system that consists of various components used in the management of pelvic, feet and long bone fractures and reconstructive and corrective orthopedic surgery. The system consists of stainless steel bone pins, composite bars, and titanium clamps. These components can be combined to build a frame which is appropriate for each specific application.

Indications for Use

The MAVERICK External Fixation System is intended to be used for temporary stabilization of the long bones, feet, and pelvis.

The indications for the Smith & Nephew MAVERICK 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 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 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 Pin Testing | Axial Grip Strength of Clamps Torsional Grip Strength of Clamps Pin Insertion Force Pin Pullout |
| Subject Clamps Testing | Torsional Grip Strength of Pins Resistance to Slip at Internal Swivel Junction Axial Grip Strength of Bars Torsional Grip Strength of Bars Axial Grip Strength with Pins |
| Subject Clamps/Post Testing | Axial Grip Strength of Clamps Torsional Grip Strength of Clamps |
| Testing of Interconnections in Full Constructs | Cyclic Testing of Pelvic Frames Cyclic Testing of Joint Spanning Style Frames |
| Rigidity Testing to Failure of Full Constructs | Load to Failure of Pelvic Frames Load to Failure of Joint Spanning Style Frames |

A 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 External Fixation System is substantially equivalent to the commercially available predicate devices.