November 16, 2020

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

Re: K201918
Trade/Device Name: EVOS Large Fragment Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, NDG
Dated: September 1, 2020
Received: September 2, 2020

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201918

Device Name
EVOS Large Fragment Plating System

Indications for Use *(Describe)*
The EVOS Large Fragment Plating System is indicated for adult patients. It is indicated for fixation of long bone fractures.

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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	June 19, 2020
	Thomas Fearnley Senior Regulatory Affairs Specialist T 901-399-1224 F 901-566-7022
Name of Device:	EVOS Large Fragment Plating System
Common Name:	Bone Plates
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:	HRS, HWC, NDG

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	**Smith & Nephew Locking Bone Plate System (PERI-LOC) Primary Predicate**	**K033669**	**December 10, 2003**
Smith & Nephew, Inc.	EVOS Small Fragment Plating System Straight Plates and Screws	K162078	November 18, 2016
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System for the Upper Extremity	K061352	June 8, 2006
Smith & Nephew, Inc.	PERI-LOC Proximal Femur Locking Bone Plates, Bone Screws and Cable Accessories	K072818	November 19, 2007
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System for Lower & Upper Extremity	K092015	July 30, 2009
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System (TC-100)	K993106	December 09, 1999

Device Description

Subject of this premarket notification is the EVOS Large Fragment Plating System. The proposed devices incorporate design features similar to those currently incorporated on previously cleared Smith & Nephew bone plate and screw systems. Like their previously cleared counterparts, the proposed plates feature a screw-to-plate locking feature that permits their use with the proposed and compatibility designed locking and non-locking screws described in this premarket notification. It is comprised of a variety of locking and non-locking 4.5mm straight plates, 3.5mm and 4.5mm anatomical plates as well as previously cleared 3.5mm locking and non-locking screws and new 4.5mm locking and non-locking screws, 5.7mm cannulated locking screws, 6.5mm locking and non-locking screws, and 6.7mm high-torque (osteopenia) screws.

Indications for Use

The EVOS Large Fragment Plating System is indicated for adult patients. It is indicated for fixation of long bone fractures.

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. The subject devices include locking and non-locking plates. Screw holes in the locking plates can either be threaded holes or variable angle holes and the non-locking plates have non-threaded holes. The subject screws feature a hex drive and are similar to existing Smith & Nephew predicate screws with respect to threadform and major and minor diameter.

Summary of Pre-Clinical Testing

- Finite element analysis (FEA) was conducted on the proposed plate designs to determine the worst case plates for further mechanical testing. Plates were separated into groups for evaluation based upon similar designs or anatomical application.
- Bending performance was evaluated through static or cantilever bend testing or construct fatigue testing for the worst case plate designs identified through FEA. Results of the testing determined that the subject plates performed similar or superior to the predicate plates tested, when evaluated under the same conditions.
- Static cantilever bending and fatigue performance of the locking mechanism for the 4.5mm screws were evaluated at a fixed angle through the threaded locking mechanism and variable angle locking holes and the results met the acceptance criteria in that they were similar or superior (higher) than the predicates.
- Torque to failure testing for the proposed 4.5mm bone screws as the worst case was conducted following the guidelines of ASTM F543. The acceptance criterion was met in that the static torsional performance of the EVOS screws was found to be similar to the static torsional performance of a previously cleared predicate device.
- Axial pull-out testing was conducted on the proposed 4.5mm, 5.7mm, 6.5mm and 6.7mm screws following the guidelines of ASTM F543. The acceptance criterion was met in that the subject screws that were tested showed similar or superior (higher) pull-out strength compared to the predicates or met the performance criteria from FDA Guidance for Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway.
- 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.

- Packaging verification testing was conducted for the proposed packaging configurations and the results of this testing demonstrated that the product will not be damaged during shipment and will adequately maintain sterility post shipment.
- Bacterial endotoxin testing was completed and met the acceptable endotoxin limits as stated in the FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," "Pyrogen and Endotoxins Testing: Questions and Answers," and ANSI/AAMI ST72.
- EVOS Large Fragment Fracture Plating System Biocompatibility Testing

Conclusion

This Traditional 510(k) premarket notification is being submitted to request clearance for the EVOS Large Fracture Plating System. Based on similarities to the predicate plating systems and a review of the mechanical testing performed, the subject devices are substantially equivalent to the predicate devices.