Smith & Nephew, Inc.
Samantha Staubach
Regulatory Affairs Specialist II
1450 Brooks Road
Memphis, Tennessee 38116

January 8, 2018

Re: K173293
Trade/Device Name: EVOS Small Fragment Upper Extremity Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 19, 2017
Received: December 20, 2017

Dear Ms. Staubach:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173293

Device Name
EVOS Small Fragment Upper Extremity Plates

Indications for Use *(Describe)*
The EVOS Small Fragment Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of small and long bone fractures, including, but not limited to, those of the tibia, fibula, femur, humerus, ulna, radius, pelvis, acetabulum, metacarpals, metatarsals, and clavicle.

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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Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 12, 2017
`	Samantha Staubach Regulatory Affairs Specialist II T 901-399-6132 F 901-566-7596
Name of Device:	EVOS Small Fragment Upper Extremity Plates
Common Name:	Bone Plates
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HRS

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	**Smith & Nephew Bone Plate System (primary predicate, now branded as TC-100)**	**K993106**	**December 9, 1999**
Smith & Nephew, Inc.	Smith & Nephew Locking Bone Plate System (now branded as PERI-LOC)	K033669	December 10, 2003
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System – B Plate Locking Bone Plates and Screws (now branded as PERI-LOC VLP)	K062216	September 15, 2006
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System –VLP Locking Bone Plates and Screws	K071563	August 8, 2007
Smith & Nephew, Inc.	EVOS Small Fragment Plating System Straight Plates and Screws	K162078	November 18, 2016
Smith & Nephew, Inc.	EVOS Small Fragment Lower Extremity Plates	K170457	June 14, 2017
Smith & Nephew, Inc.	EVOS Small Fragment Plating System	K170887	April 24, 2017

Device Description

Subject of this premarket notification is an extension of the EVOS Small Fragment Plating System, the EVOS Small Fragment Upper Extremity Plates. The subject plates feature similarities to existing Smith & Nephew small fragment plating systems (TC-100 Small Bone Plating System, PERI-LOC/PERI-LOC VLP Plating Systems) and also share some instruments and compatible implants from the existing EVOS MINI Plating System and EVOS Small Fragment Plating System. When compared against EVOS Small Fragment Plates already cleared for market, the subject plates use the same hole features and are designed to work with the same bone screws. The EVOS Small Fragment Upper Extremity Plates are available in a variety of plate designs for specific anatomical areas. These plate designs include plates with 2.7mm holes or 3.5mm holes only, or with a combination of 2.7mm and 3.5mm holes. Plate designs may include threaded holes, non-threaded holes, and variable-angle locking holes.

Indications for Use

The EVOS Small Fragment Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of small and long bone fractures, including, but not limited to, those of the tibia, fibula, femur, humerus, ulna, radius, pelvis, acetabulum, metacarpals, metatarsals, and clavicle.

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 plates designs with a variety of hole features, which are available on EVOS Small Fragment Plates previously cleared for market. The subject plates differ from the EVOS Small Fragment Plates previously cleared in that the plate shapes are more anatomically specific for upper extremity fractures.

Summary of Pre-Clinical Testing

- Finite element analysis (FEA) was conducted on the proposed plate designs to determine the worst case plates based upon structural strength for further mechanical testing. Plates were separated into groups for evaluation based upon similar designs or anatomical application.
- Bending fatigue performance or construct fatigue performance was evaluated for the worst case plate designs identified through FEA. Results of the testing determined that the subject EVOS plates performed similar or superior to the predicate plates tested, when evaluated under the same conditions.
- Engineering rationales were leveraged to justify the bending strength of some EVOS plates based on previously conducted FEA, previously conducted mechanical testing, and hand calculations.

- 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.

Conclusion

This Traditional 510(k) premarket notification is being submitted to request clearance for the EVOS Small Fragment Plating System Upper Extremity Plates. 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.