DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 14, 2017

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

Re: K170457
Trade/Device Name: EVOS Small Fragment Lower 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: May 16, 2017
Received: May 17, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170457

Device Name
EVOS Small Fragment Lower 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.

The EVOS Partial Articular and Anti-Glide plates are indicated for the treatment of partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classification Type B), and for fracture fixation of the fibula.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	February 14, 2016
	Samantha Staubach Regulatory Affairs Specialist T 901-399-6132 F 901-566-7596
Name of Device:	EVOS Small Fragment Lower 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, reference predicate)	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, reference predicate)	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 (reference predicate)	K162078	November 18, 2016

Device Description

Subject of this premarket notification is an extension of the EVOS Small Fragment Plating System, the EVOS Small Fragment Lower Extremity Plates. The subject plates feature similarities to existing Smith & Nephew small fragment plates (TC-100 Small Bone Plating System, PERI-LOC and PERI-LOC VLP Plating Systems, EVOS Small Fragment Plating System Straight Plates) and also share some instruments and compatible implants from the existing EVOS MINI Plating System and EVOS Small Fragment Plating System. EVOS Small Fragment Lower 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. The subject plates are offered in "thick" and "thin" varieties. The "thin" plates are the partial articular/antiglide plates.

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.

The EVOS Partial Articular and Anti-Glide plates are indicated for the treatment of partial articular fractures of the distal and proximal tibia (AO/OTA Fracture Classification Type B), and for fracture fixation of the fibula.

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 with both locking and non-locking holes, identical to the holes used in the EVOS Small Fragment Straight Plates cleared via K162078.

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 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.
- 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 Lower 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.