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

November 18, 2016

Smith & Nephew, Inc.
Samantha Staubach
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38119

Re: K162078
Trade/Device Name: EVOS Small 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
Dated: October 27, 2016
Received: October 28, 2016

Dear Samantha 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)*
K162078

Device Name
EVOS Small Fragment Plating System

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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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 27, 2016
	Samantha Staubach Regulatory Affairs Specialist T 901-399-6132 F 901-566-7596
Name of Device:	EVOS Small Fragment Plating System
Common Name:	Bone Plates and Screws
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

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**
Synthes (USA)	Synthes Small Fragment Dynamic Compression Locking System	K000684	April 28, 2000
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	K062216	September 15, 2006
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System Hexalobular Bone Screws	K082516	September 17, 2008

Device Description

Subject of this premarket notification is an extension to the EVOS family of plates and screws, the EVOS Small Fragment Plating System. This system features similarities to existing Smith & Nephew small fragment plates (TC-100 Small Bone Plating System, PERI-LOC Plating System) and also shares some instruments and implants from the existing EVOS MINI Plating System.

It is comprised of a variety of locking and non-locking 2.7mm and 3.5mm straight plates as well as 3.5mm locking and non-locking screws and 4.7mm non-locking osteopenia screws.

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 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 as well as the high stress region of the plate to be used for subsequent mechanical testing. The acceptance criteria were met in that the subject bone plates exhibited similar or superior structural strength compared to the existing predicates. Results of the FEA demonstrated that the plates identified for mechanical testing were the appropriate bone plates because they possessed the highest stress concentrations.
- Four point bend fatigue testing was conducted on the worst-case designs of the proposed bone plates, as identified through FEA. Results of the testing concluded that the bending fatigue performance achieved by the proposed bone plates met the acceptance criteria in that they were found to be similar to the bending fatigue performance of a previously cleared predicate.
- Torque to failure testing for the proposed 3.5mm and 4.7mm bone screws 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 4.7mm osteopenia 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.
- Static cantilever bending performance of the locking mechanism for the 3.5mm and 2.7mm screws was 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.

- Engineering rationales were leveraged for several proposed devices due to the similarity in design when compared against the predicates.
- Packaging testing was conducted for the larger pouch/carton design and the results of this testing showed 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 Straight Plates and Screws. Based on similarities to the predicate components and a review of the mechanical testing performed, the subject devices are substantially equivalent to the predicate devices.