DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 24, 2017

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

Re: K170887
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, HTN
Dated: March 24, 2017
Received: March 27, 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)*
K170887

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:	April 11, 2017
`	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, Screws, Washers
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/HTN

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	**Smith & Nephew, Inc. EVOS Small Fragment Plating System (primary predicate)**	**K162078**	**November 18, 2016**
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System (now branded as TC-100)	K993106	December 9, 1999
Smith & Nephew, Inc.	PERI-LOC Periarticular Locked Plating System for Upper Extremity	K061352	June 8, 2006
Smith & Nephew, Inc.	PERI-LOC Locking Hole Inserts and Cable Accessories	K100325	May 4, 2010
Smith & Nephew, Inc.	EVOS Mini-Fragment Plating System (Reference Predicate)	K140814	May 7, 2014
Synthes (USA)	Synthes Small Fragment Dynamic Compression Locking System	K000684	April 28, 2000

Device Description

The subject of this special premarket notification is a modification in the manufacturing process for select EVOS Small Fragment Straight Plates that were previously cleared via K162078. Also subject to this special premarket notification is the addition of EVOS 3.5mm Locking Hole Inserts and EVOS 3.5mm Washers and Double Washers. The subject devices are intended to be used with existing Smith & Nephew implants and instruments that have been previously cleared for market for use with the EVOS Small Fragment Plating System.

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

The subject devices are very similar to existing Smith & Nephew Plating System implants. Compared to the Reconstruction and Compression Plates cleared via K162078, the modified plates have minor dimensional changes and are manufactured using a slightly different manufacturing process (Plates will be manufactured from extruded stock instead of being manufactured using a sculpture milled process.) No other changes were made to the subject modified plates. The 3.5mm Washers and Double Washers and Locking Hole Inserts are designed for use with the EVOS Small Plating Fragment System. These implant accessories are similar to washers and locking hole inserts provided with other Smith & Nephew Plating Systems. 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.

Summary of Pre-Clinical Testing

- Engineering rationales were leveraged for minor design modifications to the plates to ensure that the modifications would not have a significant influence on plate strength.
- Four point bend fatigue testing was conducted on the worst-case designs of the proposed bone plates, as previously identified through FEA. Results of the testing concluded that the bending fatigue performance achieved by the proposed bone plates manufactured from extruded material met the acceptance criteria in that they were found to be similar to the bending fatigue performance of the EVOS sculpture milled plates cleared via K162078 and additional predicate plating systems.
- Four point bend fatigue testing was conducted for an EVOS Locking plate with locking hole inserts compared to an EVOS Locking plate without locking hole inserts. Based on the results of the testing, the EVOS Locking Plates with locking hole inserts are expected to have a similar or superior (higher) bending performance as the Locking Plates without locking hole inserts.
- Bacterial endotoxin levels were evaluated using the LAL method and were shown to be under 20 EU/device

Conclusion

This Special 510(k) premarket notification is being submitted to request clearance for the EVOS Small Fragment Plating System Straight Plates and implant accessories. 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.