Smith & Nephew, Inc.
Bryan Cowell
Senior Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

August 9, 2018

Re: K181533
Trade/Device Name: EVOS Wrist Fracture 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
Dated: June 7, 2018
Received: June 11, 2018

Dear Bryan Cowell:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Mark N. Melkerson -S

Mark Melkerson
Division Director
Division of Orthopedics 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)*
K181533

Device Name
EVOS Wrist Fracture Plating System

Indications for Use *(Describe)*

The EVOS Wrist Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures, malunions, and osteotomies involving the radius and ulna.

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 20, 2018
	Bryan Cowell Senior Regulatory Affairs Specialist T 978-749-1093 F 978-749-1443
Name of Device:	EVOS Wrist 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
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HRS

Predicates

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	VLP Wrist Fracture System (primary predicate)	K161665	November 15, 2016
Smith & Nephew, Inc.	D-RAD SMARTPACK	K132296	January 7, 2014
Smith & Nephew, Inc.	Bone Plate System	K993106	December 9, 1999
Smith & Nephew, Inc.	EVOS Small Fragment Plating System	K162078	November 18, 2016
Smith & Nephew, Inc.	Synthes 3.5mm Cortex Screws	K043185	February 3, 2005
Smith & Nephew, Inc.	EVOS Mini Fragment Plating System	K140814	May 7, 2014
Smith & Nephew, Inc.	Variable – Angle Locking Mini Fragment Plating System	K132886	February 4, 2014

Device Description

Subject of this premarket notification is the EVOS Wrist Fragment Plating System.
The proposed devices incorporate design features that are 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 cortex screws described in this premarket notification. Each screw hole contains five separate tabs that engage with the threads of the locking screw. The

locking screws can be angled and locked up to fifteen degrees in any direction, allowing for custom, multi-directional locked plating constructs. The subject plates can be used with screws previously cleared via K161665, K132296, K993106, K162078, K043185, K140814 and K132886 and pegs subject of this premarket notification. Refer to Section 11 Device Description for greater detail.

Indications for Use

The EVOS Wrist Plating System is indicated for adult and pediatric patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures, malunions, and osteotomies involving the radius and ulna.

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 similar to the previously cleared predicate devices K161665, K132296, K993106, K162078, K043185, K140814 and K132886.

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.

- EVOS Wrist Fracture Plating System Biocompatibility Testing

Conclusion

This Traditional 510(k) premarket notification is being submitted to request clearance for the EVOS Wrist 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.