October 18, 2022

Smith & Nephew, Inc.
Jyothsna Baravatula
Regulatory Affairs Specialist
1450 E Brooks Rd
Memphis, Tennessee 38116

Re: K213123
Trade/Device Name: EVOS Wrist Spanning Plate
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: September 13, 2022
Received: September 14, 2022

Dear Jyothsna Baravatula:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213123

Device Name
EVOS Wrist Spanning plate

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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Smith+Nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	17 November 2021
	Jyothsna Baravatula Regulatory Affairs Specialist T 901-456-5171 F 901-566-7022
Name of Device:	EVOS Wrist Spanning Plate
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.	EVOS Wrist Fracture Plating System **(Primary Predicate)**	K181533	August 09, 2018
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System (TC-100)	K993106	December 09, 1999

Device Description

The subject of this premarket notification is the EVOS Wrist Spanning Plate. The proposed device has identical indications to those previously cleared Smith & Nephew EVOS Wrist Fracture Plating system K181533 i.e. primary predicate. The proposed device incorporates design features similar to those currently incorporated on previously cleared Smith& Nephew Bone Plate System TC -100 (K993106). Like their previously cleared counterparts, the proposed plate features a screw-to-plate locking feature that permits their use with the proposed and compatibility designed locking and cortex screws described in this premarket notification. It is comprised of EVOS Wrist Spanning plate 13H, 1.8mm locking pegs, 2.4 and 3.5mm locking and cortex screws.

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 device EVOS Wrist Spanning plate and the Smith & Nephew Bone Plating System (K993106) have similar design. Both devices have same operating principle i.e. they

use pegs and screws to be attached to bone. The subject device includes EVOS Wrist Spanning plate along with locking pegs, locking and cortex screws (K132886, K181533). Screw holes in the EVOS Wrist Spanning plate can either be threaded holes or variable angle holes. The subject screws feature a hex drive and are similar to existing Smith & Nephew predicate screws with respect to thread form and major and minor diameter.

Summary of Pre-Clinical Testing

- Bending performance was evaluated using a four-point bend fatigue test identified through FEA as the worst-case scenario in accordance with the guidelines of ASTM F382. The acceptance criterion was met in that the subject plates that were tested showed similar or superior (higher) bending fatigue performance compared to the predicates.
- 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.
- Master Biological Evaluation of Titanium Plate Implant Devices

Conclusion

This Traditional 510(k) premarket notification is being submitted to request clearance for the EVOS Wrist Spanning Plate. Based on similarities to the predicate plating systems and a review ofthe mechanical testing performed, the subject devices are substantially equivalent to the predicate device.