July 22, 2020

Smith & Nephew, Inc.
Kayla Franklin
Regulatory Affairs Specialist 1
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K201527
Trade/Device Name: EVOS Straight Proximal Humerus 7-15 hole Plates (137-225mm)
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 5, 2020
Received: June 8, 2020

Dear Kayla Franklin:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201527

Device Name
EVOS Straight Proximal Humerus 7-15 hole Plates (137-225mm)

Indications for Use *(Describe)*
The EVOS Small Fragment Plating System is indicated for adult and adolescent (greater than 12-21 years of age) 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.

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510(k) Summary

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Submission:	July 22, 2020
Contact Person:	Kayla Franklin, Regulatory Affairs Specialist I T (901) 800-3398 M (901) 325-2471
Name of Device:	EVOS Straight Proximal Humerus 7-15 hole Plates (137-225mm)
Common Name:	Plate, Fixation, Bone
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
Predicate Device:	EVOS Straight Proximal Humerus Plates – K173293

Device Description:

The subject of this Traditional 510k is the EVOS Straight Proximal Humerus 7-15 hole plates (137-225mm). The EVOS Straight Proximal Humerus Plate are a line extension to the existing 3 and 5 holes EVOS Straight Proximal Humerus Plates (93-114mm). The EVOS Straight Proximal Humerus Plates were previously cleared for market via premarket notification K173293. The lengths of the subject EVOS Straight Proximal Humerus Plates are being extended to include 7-15 hole plates (137-225mm). The EVOS Straight Proximal Humerus Plates are for single use only. Similar plate lengths have been cleared on EVOS Curved Proximal Humerus 6-18 hole plates (114-246mm) via premarket notification K173293.

Indications for Use

The EVOS Small Fragment Plating System is indicated for adult and adolescent (greater than 12-21 years of age) 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 demonstrate that the subject device EVOS Straight Proximal Humerus 7-15 hole plates (137-225mm) are substantially equivalent to the below listed legally marketed predicate devices with regard to intended use, indications for use, design, material and performance characteristics.

Substantial Equivalence Information

The overall design, materials, and indications for use for the EVOS Straight Proximal Humerus 7-15 hole plates (137-225mm) are substantially equivalent to the following commercially available predicate devices.

Table 6.1: Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	72466903 EVOS 3.5mm Straight Proximal Humerus Plate 3H 93mm & 5H 114mm	K173293	01/08/2018

Performance Testing

To further support a determination of substantial equivalence, an engineering analysis was conducted on the EVOS Straight Proximal Humerus 7-15 hole plates (137-225mm). A review of the testing indicates that the EVOS Straight Proximal Humerus 7-15 hole plates (137-225mm) are substantially equivalent to predicate devices listed in the **Table 6.1** above.

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

As previously noted, this 510(k) Premarket Notification is being submitted to request clearance for the EVOS Straight Proximal Humerus 7-15 hole plates (137-225mm). Based on the similarities to the predicate devices and a review of the finite element analysis testing, the subject device is substantially equivalent to the commercially available predicate devices listed above.