July 16, 2021

Avanti Orthopaedics, Inc.
% Linda Braddon
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K211592
Trade/Device Name: Avanti Orthopaedics Ulnar Shortening 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: May 19, 2021
Received: May 24, 2021

Dear Linda Braddon:

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,

Jesse Muir -S

For: 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)*
K211592

Device Name
Avanti Orthopaedics Ulnar Shortening System

Indications for Use *(Describe)*
The Avanti Orthopaedics Ulnar Shortening System is intended for ulnar shortening osteotomy.

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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In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the Avanti Orthopaedics Ulnar Shortening System is provided below.

Date Summary Prepared	July 16, 2021
Submitter	Avanti Orthopaedics, Inc 4606 Simon Road Wilmington, DE 19803 Phone 302-530-6369 Fax 302-351-4896
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. Patricia Jones 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Avanti Orthopaedics Ulnar Shortening System
Common Name	Plate, Fixation, Bone
Classification Name	Single/Multiple component metallic bone fixation appliances and accessories
Code –Classification	HRS, 21 CFR 888.3030: Class II
Primary Predicate	K142502 New Clip Alians Ulna Locking Plating System
Additional Predicates	K141232 Medartis Aptus Ulna Shortening 2.5
Reference Device	K191118 Avanti Distal Radius and Forearm System
Device Description	The Avanti Orthopaedics Ulnar Shortening System implants are designed for wrist and forearm conditions in which the ulna is, either statically or dynamically, longer than the radius and causing pain and/or dysfunction due to derangement of the distal radioulnar joint (DRUJ) and/or impaction of the carpus. The Avanti Orthopaedics Ulnar Shortening System plates and screws are manufactured from 316LS medical grade implant quality stainless steel. The Avanti Orthopaedics Ulnar Shortening System plate should only be used with the appropriately sized Avanti Orthopaedics screws. The lag screw hole in the ulnar shortening plate provides for orthogonal, compressive fixation of the osteotomy.
Indications for Use	The Avanti Orthopaedics Ulnar Shortening System is intended for ulnar shortening osteotomy.
Technological Characteristics	The subject Avanti Orthopaedics Ulnar Shortening System is technological similar to other similarly intended devices in that it has the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.
Non-Clinical Performance Testing Conclusion	Although non-clinical testing was not necessary, an engineering analysis was provided to show the subject system did not create a new worst case as compared to the reference device K191118 Avanti Distal Radius and Forearm System.
Substantial Equivalence Summary (Conclusion)	The Avanti Orthopaedics Ulnar Shortening System has been shown to be substantially equivalent to legally marketed predicate devices.