December 13, 2019

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

Re: K191118
Trade/Device Name: Avanti Distal Radius and Forearm 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
Dated: November 13, 2019
Received: November 14, 2019

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,

Shumaya Ali
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 on last page.*

510(k) Number *(if known)*

K191118

Device Name

Avanti Distal Radius and Forearm System

Indications for Use *(Describe)*

The system intended for fixation of fractures, osteotomies, malunions, and non-unions, involving the radius, ulna, and carpals. Additionally, the wrist fusion plates may be used for wrist arthrodesis.

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.

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the *Avanti Distal Radius and Forearm System* is provided below.

Date Summary Prepared	November 13, 2019
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. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Avanti Distal Radius and Forearm System
Common Name	Single/Multiple component metallic bone fixation appliances and accessories
Code –Classification	HRS, 21 CFR 888.3030: Class II
Primary Predicate	K132704 Biomet Distal Radius Volar Rim (DVR) Plating System
Additional Predicates	K042355 Synthes LCP Wrist Fusion Plates K951304 Synthes 2.7 MM Cannulated Screw and Threaded Washer K000684 Synthes Small Fragment Dynamic Compression Locking (DCL) System K160995 In2Bones SAS Neoview Plate
Device Description	The Avanti Distal Radius and Forearm System includes volar plates, wrist fusion plates, spanning plates, forearm plates, ulnar plates, and cannulated screws, with screw and peg fasteners, for the fixation of fractures, malunions, and osteotomies. Distal radius and forearm fixation plates may be placed on the volar or dorsal surface of the radius and along the shaft of the radius and ulna on the carpal bones. Features of the system include pre-contoured plates to fit the anatomy of the distal radius, a low-profile design to minimize soft tissue irritation, low contact design to optimize blood supply, and bi-planar angulated screw holes for ease of drilling and to optimize fixation and subchrondral support. All plates are manufactured from medical grade stainless steel per ASTM F138 or ASTM F139 and are electropolished per ASTM F-86. The Volar PEEK Plate has a polyetheretherkeytone that is preassembled to the plate and is sourced from Invibio, LTD. The PEEK insert allows insertion of both locking and non-locking fasteners with an infinite variable angle up to 11 degrees using the drill guide

	provided in the system. All plates include low-profile geometry to minimize soft tissue irritation and the option of compression or locking cortical screws. The Avanti Distal Radius and Forearm System includes self-tapping screws, listed below, that are manufactured from medical grade stainless steel per ASTM F138, electropolished per ASTM F-86, and are compatible with all Avanti plate configurations. All fasteners but the Cannulated Screw are intended to be used with the plates. The cannulated screws can be used for fracture fixation that is appropriately sized for the device which is determined through surgeon discretion.
Intended Use	The system intended for fixation of fractures, osteotomies, malunions, and non-unions, involving the radius, ulna, and carpals. Additionally, the wrist fusion plates may be used for wrist arthrodesis.
Technological Characteristics	The subject *Avanti Distal Radius and Forearm 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. The subject system differences technologically in that the volar plate comes with a pre-assembled PEEK insert. The PEEK insert allows insertion of both locking and non-locking fasteners with variable angle up to 11 degrees using the drill guide provided in the system.
Non-Clinical Performance Testing Conclusion	Non-clinical testing was performed to demonstrate the *Avanti Distal Radius and Forearm System* is substantially equivalent to other predicate devices. The following tests were performed: • Static and dynamic plate loading per ASTM F382 • Screw pullout strength via ASTM F543 • Locking Mechanism Push-Out Testing
Substantial Equivalence Summary (Conclusion)	The *Avanti Distal Radius and Forearm System* has been shown to be substantially equivalent to legally marketed predicate devices.