May 9, 2026

Avanti Orthopaedics, LLC
% Justin Gracyalny
Senior Manager, Regulatory and Technical Compliance
Secure BioMed Evaluations
7828 Hickory Flat Hwy., Suite 120
Woodstock, Georgia 30188

Re: K261145
Trade/Device Name: Avanti Distal Elbow ORIF 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: April 7, 2026
Received: April 7, 2026

Dear Justin Gracyalny:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261145

Please provide the device trade name(s).

Avanti Distal Elbow ORIF System

Please provide your Indications for Use below.

The Distal Elbow ORIF System is intended for fixation of fractures of the olecranon, radius, and ulna in adults. Specifically,
• Olecranon plates are indicated for fixation of fractures and osteotomies, malunions and non-unions of the olecranon and proximal ulna.
• Straight and curved forearm plates are indicated for fixation of fractures and osteotomies of the radius and ulna.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) SUMMARY:
Avanti Distal Elbow ORIF System

Date Prepared	May 6, 2026
Sponsor	Avanti Orthopaedics, LLC 1814 Gilpin Avenue Wilmington, DE 19806
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE, RAC 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com (email)
Trade Name	Avanti Distal Elbow ORIF System
Common Name	Plate, Fixation, Bone
Regulation Number	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories. 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.
Product Code(s)	HRS, HWC
Primary Predicate	K120717 Synthes Variable Angle LCP Elbow System
Additional Predicates	K240613 Medartis AG APTUS Elbow Dorsal Olecranon Plates K983988 Syntec Scientific Corp. Syntec-Taichung Non-Sterile Titanium Alloy Mini-Plate K222967 Avanti Cannulated Compression Screw System K211592 Avanti Ulnar Shortening System K191118 Avanti Distal Radius and Forearm System
Device Description	The Avanti Distal Elbow ORIF System is a plate and screw fixation system intended for fixation of fractures and osteotomies of the olecranon, radius and proximal ulna. Plates and screws are offered in multiple sizes and configurations. Olecranon plates are offered in 5 sizes, with select offerings in both left and right configurations. Straight plates are offered in 2 sizes. Curved plates are offered in a single size in left and right configurations. All plates are compatible only with previously cleared Avanti screws. All components are manufactured from 316LS stainless steel per ASTM F138 or ASTM F139 and select plates utilize polyetheretherkeytone (PEEK) inserts to achieve variable-angle fixation.
Indications for Use Statement	The Distal Elbow ORIF System is intended for fixation of fractures of the olecranon, radius, and ulna in adults. Specifically, • Olecranon plates are indicated for fixation of fractures and osteotomies, malunions and non-unions of the olecranon and proximal ulna. • Straight and curved forearm plates are indicated for fixation of fractures and osteotomies of the radius and ulna.

Technological Characteristics	The subject device plates have the same intended use and similar technological characteristics as the identified predicate devices. The subject and predicate devices share the same intended use, principle of operation, and many other similar fundamental technological characteristics such as material, plate geometry, number of screw holes, compatible screw diameter, and compatible screw length. There are no significant technological differences between the subject and predicate device. The subject device includes minor differences in the indications for use. These differences only serve to add clarification for when specific plate offerings are appropriate for use and do not represent a change to the intended use. Minor differences in component geometry and size offerings are addressed via performance testing and via comparison to the cleared technological reference / predicate devices. The technological design features of the subject implants were compared to the primary predicate in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.
Performance Testing	The following assessments were performed to support substantial equivalence of the subject device straight / curved plates and olecranon plates: • Engineering Analysis Justification (Straight / Curved Plates) • 4-Point Bend Finite Element Analysis (Olecranon Plates) The results of these studies show that the Avanti Orthopaedics Distal Elbow ORIF System did not create a new worst case than the reference device (K191118) and/or met the performance criteria outlined in the FDA guidance "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway." No testing for the subject device screws was required to support substantial equivalence. All screws are either identical to those cleared in previous submissions or do not create a new worst case for performance testing.
Conclusion	The Avanti Orthopaedics Distal Elbow ORIF System is substantially equivalent to the legally marketed predicate device.