November 23, 2022

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

Re: K222967
Trade/Device Name: Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Screws, Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 26, 2022
Received: September 27, 2022

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 -S

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)*

K222967

Device Name

Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws

Indications for Use *(Describe)*

The Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*

K222967

Device Name

Avanti Orthopaedics 3.2mm, and 4.0mm Cannulated Compression Screws

Indications for Use *(Describe)*

The Avanti Orthopaedics 3.2mm, and 4.0mm Cannulated Compression Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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)

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510(k) SUMMARY:

Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Screws
Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Screws

Date Prepared	November 18, 2022	
Sponsor	Avanti Orthopaedics, Inc 1814 Gilpin Avenue Wilmington, DE 19806 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 Orthopaedics 2.2mm and 2.7mm Cannulated Screws Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Screws	
Common Name	Prosthetic Device	
Code – Classification	Product Code: HWC Regulation: 21 CFR 888.3040 Device Class: II	
Primary Predicate	**Subject Device**	**Primary Predicate**
	Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws	K161616 DePuy Synthes 2.4 mm Cannulated Screws
	Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws	K161616 DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws
Additional Predicate	**Subject Device**	**Additional Predicate(s)**
	Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws	K180541 DePuy Synthes 2.0 mm Quick Insertion Screws
	Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws	K162825 CAPTIVATE™ Compression Screws
Reference Device	**Subject Device**	**Reference Device(s)**
	Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws	K191118 Avanti Distal Radius and Forearm System
	Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws	K191118 Avanti Distal Radius and Forearm System

Device Description	The Avanti Orthopaedics Cannulated Compression Screw System are metallic bone screws manufactured from Stainless Steel (ASTM F138). The screws are available in multiple lengths and diameters, and are intended to be used as stand-alone bone screws for internal bone fixation of fractures, fusions, osteotomies, non-unions, and malunions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation. The Avanti Orthopaedics Cannulated screws are cannulated for use with guidewires for precise placement in bone.
Indications for Use Statement	Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws: The Avanti Orthopedics 2.2 mm and 2.7mm Cannulated Compression Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation. Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws: The Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones and small bone fragments in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Comparison of Technological Characteristics: Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws

Characteristic	Subject Device Avanti Orthopaedics 2.2mm and 2.7mm Cannulated Compression Screws	Primary Predicate Synthes USA Products, LLC DePuy Synthes 2.4 mm Cannulated Screws K161616
Device Classification	Class II	Class II
Product Code	HWC	HWC
Purpose	Subject device	Same indications
Diameter (mm)	2.2 – 2.7mm	2.4mm
Lengths (mm)	14 – 60mm	10 – 50mm
Partially / Fully Threaded	Partially Threaded Fully Threaded	Partially Threaded Fully Threaded
Head Type	Headless	Low-Profile
Driver Shape	Star	Star
Cannulated	Yes	Yes
Self-Tapping	Yes	Yes
Sterility	End-User Sterilized, Steam Sterilization Cycle: Pre-Vacuum Temperature: 132°C (270°F) Exposure Time: 4 minutes Drying Time: 60 minutes	End-User Sterilized, Steam Sterilization
Material	Stainless Steel per ASTM F138	Stainless Steel per ASTM F138
Manufacturing	Subtractive manufacturing	Subtractive manufacturing
Biocompatibility	Implant: Permanent Duration - Implant for Tissue / Bone (>30 days) Instrument: Limited Duration - Implant for Tissue / Bone (< 24 hours)	Implant: Permanent Duration - Implant for Tissue / Bone (>30 days) Instrument: Limited Duration - Implant for Tissue / Bone (< 24 hours)
Indicated Patient Population	Adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.	Adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Comparison of Technological Characteristics: Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws

Characteristic	Subject Device Avanti Orthopaedics 3.2mm and 4.0mm Cannulated Compression Screws	Primary Predicate Synthes USA Products, LLC DePuy Synthes 3.5 mm and 4.0 mm Cannulated Screws K161616
Device Classification	Class II	Class II
Product Code	HWC	HWC
Purpose	Subject device	Same indications
Diameter (mm)	3.2 – 4.0mm	3.5 – 4.0mm
Lengths (mm)	14 – 60mm	10 – 50mm
Partially / Fully Threaded	Partially Threaded Fully Threaded	Partially Threaded Fully Threaded
Head Type	Headless	Low-Profile
Driver Shape	Star	Hex
Cannulated	Yes	Yes
Self-Tapping	Yes	Yes
Sterility	End-User Sterilized, Steam Sterilization Cycle: Pre-Vacuum Temperature: 132°C (270°F) Exposure Time: 4 minutes Drying Time: 60 minutes	Terminally Sterilized, Gamma Irradiation
Material	Stainless Steel per ASTM F138	Stainless Steel per ASTM F138
Manufacturing	Subtractive manufacturing	Subtractive manufacturing
Biocompatibility	Implant: Permanent Duration - Implant for Tissue / Bone (>30 days) Instrument: Limited Duration - Implant for Tissue / Bone (< 24 hours)	Implant: Permanent Duration - Implant for Tissue / Bone (>30 days) Instrument: Limited Duration - Implant for Tissue / Bone (< 24 hours)
Indicated Patient Population	Adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.	Adults and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

Technological Characteristics

There are no significant technological differences between the subject and predicate devices. The subject device uses the same material as the additional predicate and reference device and all devices are manufactured using subtractive techniques. Any differences in available sizes between the subject and predicate devices were addressed via the additional predicates (K180541, K162825).

Non-Clinical Performance Testing Summary

Testing was performed per ASTM F543-17 and the device met all predetermined acceptance criteria as defined in the FDA guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway".

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.