March 10, 2026

Synthes GmbH
Gengqiao Peng
Senior Regulatory Affairs Specialist
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K254093
Trade/Device Name: DePuy Synthes VOLT™ Medial Distal Femur 3.5 Plating 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: December 19, 2025
Received: December 19, 2025

Dear Gengqiao Peng:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254093

Device Name
DePuy Synthes VOLT™ Medial Distal Femur 3.5 Plating System

Indications for Use *(Describe)*

The VOLT™ Medial Distal Femur 3.5 Plating System is indicated for internal fixation of isolated medial condylar fractures as a standalone fixation device. For all other distal femur fractures, corrective osteotomies, non-unions, or malunions, it is indicated for use as an adjunct to primary fixation.

The VOLT™ Medial Distal Femur 3.5 Plating System is intended for adults and adolescents (12-21 years) in which growth plates (physes) have fused or in which unfused growth plates will not be compromised by 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

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510(K) SUMMARY

Sponsor	Synthes GmbH, Luzernstrasse 21 4528 Zuchwil, Switzerland
Contact	Gengqiao Peng Senior Regulatory Affairs Specialist T: +41 76 568 08 53 E: gpeng1@its.jnj.com
Alternate Contact	Joanna Buttler Manager Regulatory Affairs T: +41 79 721 7580 E: JButtler@its.jnj.com
Date Prepared	December 16, 2025
Proprietary Name	DePuy Synthes VOLT™ Medial Distal Femur 3.5 Plating System
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Classification	Class II Regulation Numbers: 21 CFR §888.3030 Product Codes: HRS
Predicate Device	Primary Predicate Device: • K233665 - DePuy Synthes VOLT Small Fragment Plating System Additional Predicate Device: • K082807 – Synthes (USA) 3.5 and 4.5 mm Locking Compression Plate System with Expanded Indications
Device Description	The DePuy Synthes VOLT™ Medial Distal Femur 3.5 Plating System is a family of implantable devices consisting of 3.5mm anatomic Medial Distal Femur plates with variable angle screw holes. These plates are available in Stainless Steel, supplied sterile, and intended for single use only. These plates accept VOLT™ Stainless Steel screws, including VOLT™ 3.5 mm locking, 3.5 mm cortical, and 4.0 mm cancellous screws.

Indications for Use	The VOLT™ Medial Distal Femur 3.5 Plating System is indicated for internal fixation of isolated medial condylar fractures as a standalone fixation device. For all other distal femur fractures, corrective osteotomies, non-unions, or malunions, it is indicated for use as an adjunct to primary fixation. The VOLT™ Medial Distal Femur 3.5 Plating System is intended for adults and adolescents (12-21 years) in which growth plates (physes) have fused or in which unfused growth plates will not be compromised by fixation.
Contraindications	No contraindications specific to these devices.
Non-Clinical Performance Testing	To demonstrate the safety and efficacy of the subject devices and support the substantial equivalence to their predicates, the following testing was performed: • Computational Finite Element Analysis simulating a mechanical static bending construct test, demonstrated subject plates were non-inferior regarding their yield load. • Magnetic Resonance compatibility testing has been performed to establish MR Conditional parameters for the subject VOLT™ Medial Distal Femur 3.5 Plating System.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The subject devices have the same intended use and similar indications as their predicate devices. Additionally, the subject devices are an iteration on prior DePuy Synthes plating systems and are therefore similar in terms of design, material, and fundamental technology. The non-clinical performance data and analytic evaluations included in this premarket notification demonstrate that any differences in technological characteristics of the subject device compared to the predicate device do not raise any new questions of safety and effectiveness. The proposed devices are at least as safe and effective as the predicate devices.
Conclusion	It is concluded that the information provided demonstrates the substantial equivalence of the subject devices to their predicate devices.