March 9, 2026

Synthes GmbH
Enrico Gindro, PhD
Senior Regulatory Affairs Program Lead
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K260069
Trade/Device Name: DePuy Synthes VOLT™ Proximal Tibia 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: January 9, 2026
Received: January 9, 2026

Dear Enrico Gindro:

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)*

K260069

Device Name

DePuy Synthes VOLT™ Proximal Tibia 3.5 Plating System

Indications for Use *(Describe)*

The DePuy Synthes VOLT™ Proximal Tibia 3.5 Plating System is indicated for internal fixation of proximal tibia fractures in adults and adolescents (12-21 years) where growth plates have fused.

VOLT Proximal Tibia Plates:
Indicated for fractures of the proximal end segment of the tibia.

VOLT Proximal Tibia Plates, Long:
Indicated for fractures of the proximal end segment of the tibia with or without extension into the diaphysis.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY

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|---|---|
| Sponsor | Synthes GmbH<br>Luzernstrasse 21<br>4528 Zuchwil (SO)<br>Switzerland |
| Contact | Enrico Gindro, PhD<br>Senior Regulatory Affairs Program Lead<br>T: +41 79 912 73 59<br>E: egindro@its.jnj.com |
| Alternate Contact | Oliver Steiner, PhD<br>Director Regulatory Affairs<br>T: + 41 79 229 31 83<br>E: osteiner@its.jnj.com |
| Date Prepared | January 09, 2026 |
| Proprietary Name | DePuy Synthes VOLT™ Proximal Tibia 3.5 Plating System |
| Classification Name | Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener |
| Classification | Class II<br>Regulation Number: 21 CFR §888.3030<br>Product Code: HRS |
| Predicate Device | Primary predicate:<br>• K233665 – DePuy Synthes VOLT Small Fragment Plating System<br>Additional predicates:<br>• K011978 – Synthes LCP Proximal Tibia Plate<br>• K050646 – Synthes (USA) 3.5/4.5mm LCP Medial Proximal Tibia Plates<br>• K082624 – Synthes (USA) 3.5mm LCP Posteromedial Proximal Tibia Plates |
| Device Description | The DePuy Synthes VOLT™ Proximal Tibia 3.5 Plating System comprises implantable devices intended for the stabilization and internal fixation of proximal tibia fractures. The system offers five families of stainless steel 3.5-mm contoured plates with variable angle screw holes. Plates within the VOLT™ Proximal Tibia 3.5 Plating System are available in various lengths, sterile or non-sterile, and are single-use only. The system also includes non-implantable, dedicated guide blocks, sizing templates, and trays as accessories for use with the implants. |
| Indications for Use | The DePuy Synthes VOLT™ Proximal Tibia 3.5 Plating System is indicated for internal fixation of proximal tibia fractures in adults and adolescents (12-21 years) where growth plates have fused.<br>VOLT Proximal Tibia Plates:<br>Indicated for fractures of the proximal end segment of the tibia.<br>VOLT Proximal Tibia Plates, Long:<br>Indicated for fractures of the proximal end segment of the tibia with or without extension into the diaphysis. |
| Contraindications | No contraindications specific to these devices. |

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| 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:<br>• Computational Finite Element Analysis simulating a mechanical static bending construct test, demonstrated subject plates were non-inferior regarding their bending moment and stiffness.<br><br>Additionally, Magnetic Resonance compatibility testing has been performed to establish MR Conditional parameters for the subject VOLT™ Proximal Tibia 3.5 Plating System. |
| Clinical Performance Data | Clinical testing was not necessary for the determination of substantial equivalence. |
| Substantial Equivalence | The subject devices share the same intended use and similar indications as the predicate devices. The subject and predicate devices are metallic orthopedic plates intended for bone fracture fixation and are similar in design and fundamental technology. Both the subject and predicate devices are made from the same material and are intended for use by surgeons in a healthcare facility.<br>The non-clinical performance data and analytical evaluations included in this premarket notification demonstrate that any differences in technological characteristics between the subject devices and the predicate devices do not raise 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 demonstrate the substantial equivalence of the subject devices to their predicate devices. |