July 26, 2024

Synthes GmbH
Brendan Daly
Senior Regulatory Affairs Program Lead
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K233994
Trade/Device Name: VOLT™ Proximal Humerus 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: June 11, 2024
Received: June 12, 2024

Dear Brendan Daly:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233994

Device Name

DePuy Synthes VOLT™ Proximal Humerus 3.5 Plating System

Indications for Use *(Describe)*

The DePuy Synthes VOLT™ Proximal Humerus 3.5 Plating System is indicated for internal fixation of proximal humerus fractures in adults and adolescents (12-21 years) where growth plates have fused.
VOLT™ Proximal Humerus Plates:
Indicated for fractures of the proximal end segment of the humerus.
VOLT™ Proximal Humerus Plates, Long:
Indicated for fractures of the proximal end segment and/or diaphyseal segment of the humerus.

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 OF THE DEPUY SYNTHES VOLT™ Proximal Humerus 3.5 Plating System

Sponsor	Synthes GmbH, Luzernstrasse 21, 4528 Zuchwil, Switzerland.
Contact	Brendan Daly, PhD Senior Regulatory Affairs Program Lead T: +41 76 516 35 26 E: bdaly3@its.jnj.com
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Date Prepared	July 23, 2024
Proprietary Name	DePuy Synthes VOLT™ Proximal Humerus 3.5 Plating System
Classification Name	Single component metallic bone fixation appliances and accessories
Classification	Class II Regulation Numbers: 21 CFR §888.3030 Product Codes: HRS
Predicate Device	Primary Predicate Device: • K011815 - Synthes (USA) LCP Proximal Humerus Plate Additional Predicate Device: • K041860 - Synthes (USA) LCP Proximal Humerus Plate, Long Reference Device: • K233665 - DePuy Synthes VOLT™ Mini Fragment Plating System / DePuy Synthes VOLT™ Small Fragment Plating System
Device Description	The DePuy Synthes VOLT™ Proximal Humerus 3.5 Plating System is a family of implantable devices consisting of 3.5mm anatomic plates with variable angle screw holes. The plates of this system are available in Stainless Steel and Commercially Pure Titanium, whilst the corresponding screws (locking, cortex, cancellous) are available in Stainless Steel and Titanium Alloy (TAV) respectively. Plates within the VOLT™ Proximal Humerus 3.5 Plating System are available either sterile or non-sterile and are single-use only.
Indications for Use	The DePuy Synthes VOLT™ Proximal Humerus 3.5 Plating System is indicated for internal fixation of proximal humerus fractures in adults and adolescents (12-21 years) where growth plates have fused. VOLT™ Proximal Humerus Plates: Indicated for fractures of the proximal end segment of the humerus. VOLT™ Proximal Humerus Plates, Long: Indicated for fractures of the proximal end segment and/or diaphyseal segment of the humerus.

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 bending moment and stiffness. • Magnetic Resonance compatibility testing has been performed to establish MR Conditional parameters for the subject VOLT™ Proximal Humerus 3.5 Plating System.
Summary of Technological Characteristics	The subject devices are an iteration on prior DePuy Synthes plating systems. Hence, the subject devices have the same technological characteristics in terms of design, material, and fundamental technology as that of the predicate devices. The plates are offered in similar shapes, number of holes, accepted screw sizes, and are in the same materials as that of the predicate devices. However, there are some differences: 1. Dimensions: The plate cross sections have been adjusted. 2. 3.5mm VOLT™ Locking Hole: The locking hole technology present on the VOLT™ plates is the VOLT™ Locking Hole which is a poly-axial hole that iterates on the previous Variable Angle Locking Compression Plate (VA-LCP) hole design by DePuy Synthes.
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 demonstrate the substantial equivalence of the subject devices to their predicate devices.