Synthes (USA) Products, LLC
Stephan Jepards
Sr. Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

October 24, 2018

Re: K180213
Trade/Device Name: Titanium TomoFix Medial High Tibia Plate Anatomical
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: September 18, 2018
Received: September 19, 2018

Dear Stephan Jepards:

This letter corrects our substantially equivalent letter of October 19, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S
2018.10.24 09:33:50 -04'00'

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180213

Device Name

Titanium TomoFix™ Medial High Tibia Plate Anatomical (line extension to the existing Synthes TomoFix Osteotomy System)

Indications for Use *(Describe)*

The TOMOFIX™ Medial High Tibia Plates are indicated for open- and closed-wedge osteotomies, fixation of fractures, and malalignment caused by injury or disease of the medial proximal tibia for the treatment of:
- Unicompartmental medial or lateral gonarthrosis with malalignment of the proximal tibia
- Idiopathic or posttraumatic varus or valgus deformity of the proximal tibia

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

Date Prepared: September 17, 2018

Sponsor:	DePuy Synthes Stephan Jepards 1301 Goshen Parkway West Chester, PA 19380 Office: +41 32 720 41 59
Proprietary Name:	Titanium TomoFix™ Medial High Tibia Plate Anatomical (to be included within the Synthes TomoFix™ Osteotomy System)
Device common name	Bone plate
Classification:	Classification: Class II Regulation Number: 21 CRF §888.3030 Product Code: HRS
Classification Name	Single/multiple component metallic bone fixation appliances and accessories.
Predicate Device	Titanium TomoFix™ Medial High Tibia Plate initially cleared via K023941
Reference device	TomoFix™ Medial High Tibia Plate, Small, initially cleared via K100676
Device Description:	The subject Titanium TomoFix™ Medial High Tibia Plate Anatomical is anatomically precontoured to fit the medial side of the proximal tibia (also referred to as high tibia) and is provided in a 'left' and 'right' version to accommodate the anatomy of the tibia in the left and right knee, respectively. The plate features seven round, threaded locking holes to provide a locked, fixed-angle construct and one combination locking / dynamic compression hole to allow temporary compression during the surgery. The subject plate is designed to accept existing, previously cleared 5.0 mm Locking Screws, 4.5 mm Cortex Screws and 5.0 mm Spacers
Indications for Use:	The TOMOFIX™ Medial High Tibia Plates are indicated for open- and closed-wedge osteotomies, fixation of fractures, and malalignment caused by injury or disease of the medial proximal tibia for the treatment of: • - Unicompartmental medial or lateral gonarthrosis with malalignment of the proximal tibia • - Idiopathic or posttraumatic varus or valgus deformity of the proximal tibia

Comparison to Predicate	The subject device and the predicate are identical with respect to indications and intended use. The subject Titanium TomoFix™ Medial High Tibia Plate Anatomical feature equivalent characteristics as the predicate devices. Specifically, identical technological characteristics are as follows: • Plates are compatible with 5.0 mm Locking Screws for angular, stable fixation • Plates are compatible with 4.5 mm Cortex Screws to allow temporary compression of the lateral hinge • Plates are offered sterile and non-sterile The differences in design features between the subject plates and the predicate and reference devices are listed below. • The subject plates are available in a pre-shaped left and right version to accommodate the anatomy of the left and right tibia, respectively. • The subject plates only feature one LCP combination-hole, where the predicate and reference devices each feature three LCP combination-hole in total.
Substantial Equivalence:	The subject Titanium TomoFix™ Medial High Tibia Plate Anatomical has identical indications compared to the predicate device. The features of the subject device are substantially equivalent to the predicate device based on the similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the subject device to the predicate device. In addition, the intended use, packaging, and sterilization of the predicates compared to the subject devices are identical. The subject and predicate devices are both made from commercially pure titanium grade 4 (TiCP4) in accordance with ASTM F67, UNS R50700. Mechanical testing demonstrates that the proposed Titanium TomoFix™ Medial High Tibia Plate Anatomical is substantially equivalent in mechanical properties to the predicate device. The subject device was tested under static and dynamic loading conditions to demonstrate mechanical equivalence compared to the predicate device. In conclusion, the indications, technological characteristics, and performance testing demonstrate substantial equivalence of the subject Titanium TomoFix™ Medial High Tibia Plate Anatomical.