

K120689

JUN - 4 2012



3.0 510(k) Summary

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- Sponsor:** Synthes
Thomas N. Shea
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6809
- Device Name:** Synthes 3.5 mm VA-LCP Proximal Tibia Plate System
- Classification:** Product Code – HRS/HWC, Plate, Fixation, Bone, Class II, §888.3030 – (Single/multiple component metallic bone fixation appliances and accessories.)
- Predicate Devices:** Synthes 4.5mm LCP Proximal Tibia Plate **K011978**
Synthes LCP Proximal Tibia Plate **K052390**
Synthes Large Fragment Dynamic Compression Locking (DCL) System **K000682**
OrthoPediatrics PediLoc™ Locking Plate System **K083286**
- Device Description:** The Synthes 3.5 mm VA-LCP Proximal Tibia Plate System consists of pre-contoured bone fixation plates intended for the treatment of fractures of the proximal tibia. Variable angle screws can be angled up to 15 degrees from the normal trajectory prior to locking the screw to the plate. Percutaneous instrumentation will allow the variable angle plates and screws to be applied through minimally invasive techniques.
- Intended Use:** The Synthes 3.5 mm VA-LCP Proximal Tibia Plates are intended to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused including: simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. Plates can also be used for treatment of nonunions, malunions, tibial osteotomies and osteopenic bone.
- Substantial Equivalence:** Information presented supports substantial equivalence of the Synthes 3.5 mm VA-LCP Proximal Tibia Plate System to the predicate devices, Synthes 4.5mm LCP Proximal Tibia Plate **K011978**, Synthes Large Fragment Dynamic Compression Locking (DCL) System **K000682**, and Orthopediatrics PediLoc Locking Plate System **K083286**. The proposed tibia plates have the same indications for use, are similar in shape/design and incorporate the same fundamental technology.

Static and dynamic construct testing was conducted on the proposed plates and screws in order to demonstrate comparable mechanical performance to the predicate. The mechanical testing was designed to assess the fatigue strength and bending moment of the subject device.



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The results of the mechanical evaluation confirm that the subject device is substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA) Products LLC
% Mr. Thomas N. Shea
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

JUN - 4 2012

Re: K120689

Trade/Device Name: Synthes 3.5 mm VA-LCP Proximal Tibia Plate 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, HWC
Dated: March 2, 2012
Received: March 6, 2012

Dear Mr. Shea:

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. 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); good manufacturing practice requirements as set

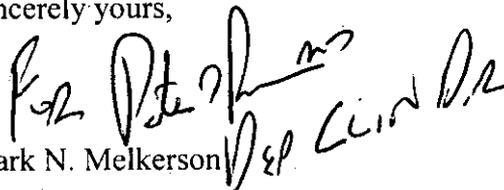
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120689



2.0 Indications for Use

510(k) Number (if known): K120689

Device Name: Synthes 3.5 mm VA-LCP Proximal Tibia Plate System

Indications for Use:

The Synthes 3.5 mm VA-LCP Proximal Tibia Plates are intended to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused including: simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. Plates can also be used for treatment of nonunions, malunions, tibial osteotomies and osteopenic bone.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

BAP for
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120689