

K092556



3.0 510(k) Summary

Page 1 of 1

Sponsor: Synthes (USA)
Karl J. Nittinger
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6941

NOV 17 2009

Device Name: Synthes (USA) 2.4mm VA-LCP Two-Column Narrow Volar Distal Radius Plates

Classification: Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.

Predicate Device: Synthes 2.4mm VA-LCP Two-Column Volar Distal Radius Plates
Synthes Variable Angle Locking Distal Radius System
Synthes Locking Distal Radius Plating System
Stryker-Leibinger Universal Distal Radius System

Device Description: The Synthes 2.4mm VA-LCP Two-Column Narrow Volar Distal Radius Plates are metallic plates intended for treatment of various fracture modes of the distal radius. The plates incorporate variable-angle locking hole technology and are available in versions composed of stainless steel and titanium.

Intended Use: Synthes 2.4mm VA-LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

Substantial Equivalence: Information presented supports substantial equivalence.



Synthes (USA)
% Mr. Karl J. Nittinger
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

NOV 17 2009

Re: K092556

Trade Name: Synthes (USA) 2.4mm VA- LCP Two-Column Narrow Volar Distal Radius Plates

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Codes: HRS, HWC

Dated: August 18, 2009

Received: August 20, 2009

Dear Mr. Nittinger:

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.

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 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.

Page 2 – Mr. Karl J. Nittinger

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,



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

Enclosure



2.0

Indications for Use

510(k) Number (if known): K092556

Device Name: Synthes (USA) 2.4mm VA-LCP Two-Column Narrow Volar Distal Radius Plates

Indications for Use:

Synthes 2.4mm VA-LCP Two-Column Narrow Volar Distal Radius Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature] for *mxm*
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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