

3.0 510(k) SummaryPage 1 of 1

Sponsor: Synthes (USA)
Sheri L. Musgnung
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6940

Device Name: Synthes Variable Angle- Locking Compression Plate (VA-LCP)
Distal Radius System

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

Predicate Device: Synthes Volar LCP Distal Radius Plates
Stryker Leibinger's Volar Plates

Device Description: Synthes VA-LCP Distal Radius System consists of machined metallic plates and screws that offer screw to plate locking designed for various fracture modes of the distal portion of the radius.

Synthes VA-LCP Distal Radius System enhances fragment-specific fracture fixation by providing the flexibility to lock screws in trajectories that can diverge from the central axis of the plate hole.

Intended Use: Synthes VA-LCP Distal Radius System is 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2007

Synthes (USA)
% Ms. Sheri L. Musgnung
Sr. Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K071184

Trade/Device Name: Synthes Variable Angle – Locking Compression Plate (VA – LCP)
Distal Radius System

Regulation Number: 21 CFR 888.3030

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

Regulatory Class: II

Product Code: HRS

Dated: April 27, 2007

Received: April 30, 2007

Dear Ms. Musgnung:

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 such 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); good manufacturing practice requirements as set

Page 2 - Ms. Sheri L Musgnung

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

2.0

Indications for Use

510(k) Number (if known): K071184

Device Name: Synthes Variable Angle-Locking Compression Plate (VA-LCP) Distal Radius System

Indications for Use:

Synthes VA-LCP Distal Radius System is 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)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K071184