SYNTHES®

OCT 27 2004

K042355

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name:

Synthes (USA) LCP Wrist Fusion Plates

Classification:

Class II, 21 CFR §888.3030
Single/multiple component metallic bone fixation appliances and accessories

Predicate Device:

Synthes Straight Wrist Fusion Plate, 170 mm

Device Description:

The Synthes LCP Wrist Fusion Plates are pre-contoured with a limited contact design utilizing a short bend with a 3.3 mm thickness and a width of 11 mm. The plate uses a total of 10 combination holes which utilizes 2.7 mm and 3.5 mm cortex and locking screws. The plates are available in Titanium and Stainless Steel.

Intended Use:

Synthes (USA) LCP Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

Substantial Equivalence:

Documentation is provided which demonstrates that Synthes LCP Wrist Fusion Plates are substantially equivalent to other legally marketed Synthes devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K042355
Trade/Device Name: Synthes (USA) LCP Wrist Fusion Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/ multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: HRS
Dated: August 30, 2004
Received: August 31, 2004

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 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

Indications for Use

510(k) Number (if known):

Device Name: Synthes (USA) LCP Wrist Fusion Plates

Indications: Synthes (USA) LCP Wrist Fusion Plates are intended for wrist arthrodesis and fractures of other small bones. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (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)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042355

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