

SEP - 8 2004

## 3.0 510(k) Summary

- Sponsor:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700
- Device Name:** Synthes (USA) LCP® Proximal Humerus Plates, Long
- Classification:** Class II, 21 CFR §888.3030  
Single/multiple component metallic bone fixation appliances and accessories
- Predicate Device:** Synthes LCP Proximal Humerus Plates  
Synthes Small Fragment DCL System
- Device Description:** The Synthes LCP Proximal Humerus Plates, long are pre-contoured to match the anatomy of the proximal humerus with a limited contact low profile design. The plate features locking holes and combination locking and compression holes which accept 2.7, 3.5, & 4.0 mm cortex screws, 3.5 mm locking screws, and 4.0 mm cancellous screws. The System will be available in Stainless Steel and Titanium. These plates will be offered as an addition to the Synthes Small Fragment LCP (formerly DCL) System.
- Intended Use:** Synthes (USA) LCP Proximal Humerus Plate, long is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.
- Substantial Equivalence:** Documentation is provided which demonstrates that Synthes LCP Proximal Humerus Plates, long is substantially equivalent to other legally marketed Synthes devices.



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

Re: K041860  
Device Name: Synthes (USA) LCP® Proximal Humerus Plates, long  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Code: HRS, HWC  
Dated: July 8, 2004  
Received: July 9, 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.

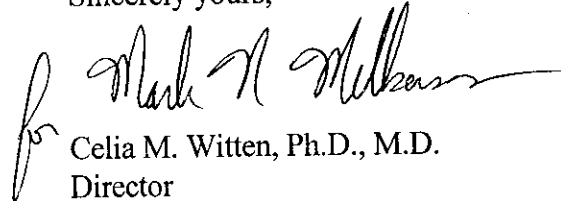
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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



**Indications for Use**

510(k) Number (if known): K041860

Device Name: Synthes (USA) LCP® Proximal Humerus Plates, long

Indications: Synthes (USA) LCP Proximal Humerus Plate, long is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

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)

*for Mark A. Melkers*  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K041860

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