

SEP - 6 2001

KO11815

3. Summary of Safety and Effectiveness Information [510(k) Summary]

<b>Sponsor</b>	Synthes (USA) 1690 Russell Road Paoli, PA 19301
<b>Company Contact</b>	Matthew M. Hull (610) 647-9700 ext. 7191
<b>Name of the Device</b>	Synthes LCP Proximal Humerus Plate
<b>Regulation &amp; Classification</b>	Class II, §888.3030 – Plate, Fixation, Bone, Non-spinal, Metallic Product code: NDF
<b>Predicate Device(s)</b>	- Synthes Small Fragment Dynamic Compression Locking (DCL) System - De Puy Ace Symmetry Proximal Humerus Plate
<b>Device Description</b>	The Synthes LCP Proximal Humerus Plates are designed to match the anatomy of the proximal humerus. These plates can be applied to either the right or left humerus. The proximal portion of each plate has threaded holes that accept 3.5 mm or 2.7 mm screws. The distal portion of the plate has combination holes that allow the option of using 3.5 mm locking or cortex screws, or 4.0 mm cancellous screws to accomplish plate fixation. These plates will be offered as an addition to the Synthes Small Fragment LCP (formerly DCL) System.
<b>Intended Use</b>	Synthes LCP Proximal Humerus Plate is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.
<b>Material(s)</b>	The LCP Proximal Humerus Plates will be available in either Stainless Steel or Titanium versions as are the other plates in the Synthes Small Fragment LCP System.



This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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

2. Indications for Use Statement

510(k) Number (if known): K011815

Device Name: Synthes LCP Proximal Humerus Plate

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

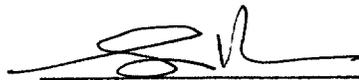
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

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

510(k) Number K011815