

K012114

SEP 28 2001

3. Summary of Safety and Effectiveness Information

<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 Locking Distal Radius Plating System
<b>Device Classification(s)</b>	Class II, §888.3030 – Plate, Fixation, Bone Class II, §888.3040 – Screw, Fixation, Bone
<b>Predicate Device</b>	- Synthes Distal Radius Plate System
<b>Device Description</b>	The Synthes Locking Distal Radius Plating System consists of machined metallic plates and screws that offer screw to plate locking designed for various fracture modes of the distal end of the radius.
<b>Indications</b>	The Synthes Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.
<b>Materials</b>	Plates: Stainless Steel or Titanium Screws: Titanium or Stainless Steel



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 28 2001

Mr. Matthew M. Hull, RAC  
Senior Regulatory Specialist  
Synthes, USA  
1690 Russell Road  
P. O. Box 1766  
Paoli, Pennsylvania 19301

Re: K012114

Trade/Device Name: Synthes Locking Distal Radius Plating System

Regulation Number: 888.3030, 888.3040

Regulation Name: Plate, fixation, bone  
Screw, fixation, bone

Regulatory Class: II

Product Code: HRS, HWC

Dated: July 5, 2001

Received: July 6, 2001

Dear Mr. Hull:

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.

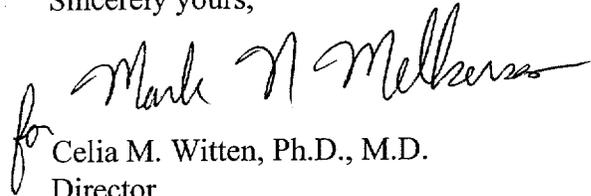
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

K012114

2. Indications for Use Statement

510(k) Number (if known):

K012114

Device Name:

Synthes Locking Distal Radius Plating System

Indications for Use:

The Synthes Locking Distal Radius Plating System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

*for* Mark N. Melkers

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

510(k) Number K012114