

AUG 21 2003

K031677

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3. 510(k) Summary:

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
Contact	Bonnie Smith
Device Name	Synthes (USA) Clavicle Hook Plate
Device Classification	21 CFR 888.3030 – Single/multiple component metallic bone fixation appliance and accessories
Predicate Device	Synthes Small T- Plate, Synthes LCP T-Plate and Howmedica's Bosworth Screw
Description of Device	Synthes Clavicle Hook Plate is an anatomically designed L-shaped plate featuring a distal joint bridging hook with a rounded end. The shaft of the plate contains either dynamic compression screw holes or LCP plate holes. The plates accept 3.5 mm cortex, 4.0 mm cancellous and 3.5 mm locking screws (LCP Clavicle Hook Plate only).
Indications	Intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint
Material	316L Stainless Steel Titanium
Substantial Equivalence	Documentation is provided which demonstrates that the Synthes Clavicle Hook Plate is substantially equivalent* to other legally marketed Synthes devices.

* The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K031677
Trade/Device Name: Synthes Clavicle Hook Plate
Regulation Numbers: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: HRS
Dated: May 29, 2003
Received: May 30, 2003

Dear Ms. Smith:

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.

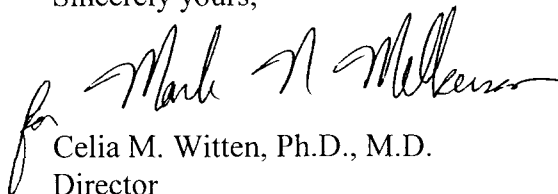
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

510(k) Number (if known): K031677

Device Name: Synthes Clavicle Hook Plate

Indications for Use: Intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

(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. Millerson

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

510(k) Number K031677
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