

APR 1 2 2004

k040765
page 1 of 1

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

SPONSOR: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Lisa M. Boyle

DEVICE NAME: Synthes 5.0/7.3 mm Cannulated Locking Screws

CLASSIFICATION: Class II § 21 CFR 888.3040: Smooth or Threaded Metallic Bone Fixation Fastener.

PREDICATE DEVICE: Synthes 5.0/7.3 mm Cannulated Locking Screws

DEVICE DESCRIPTION: The Synthes 5.0/7.3 mm Cannulated Locking Screws feature self-drilling and self-tapping tips, have a flat head profile with rounded edges with a hex drive recess. They are available in additional lengths ranging from 100 - 145mm. The threads below the head of each locking screw are designed to engage with the threaded holes of currently marketed Synthes LCP® plating systems.

INTENDED USE: Synthes 5.0/7.3 mm Cannulated Locking screws are intended to be used with existing Synthes LCP® plating systems for the fixation of various long bones, such as the femur.

SUBSTANTIAL EQUIVALENCE: Comparative information presented supports substantial equivalence.

MATERIAL: Stainless Steel



APR 1 2 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K040765

Trade/Device Name: Synthes (USA) 5.0/7.3 mm Cannulated Locking Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: March 24, 2004
Received: March 25, 2004

Dear Ms. Boyle:

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.

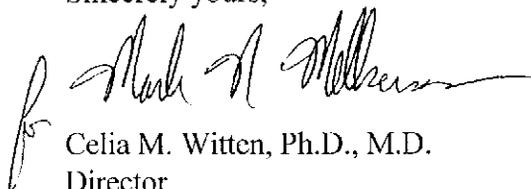
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 -- Ms. Lisa M. Boyle

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

2.0 Indications for Use Statement

510(k) Number (if known): K040765

Device Name: Synthes (USA) 5.0/7.3 mm Cannulated Locking Screw

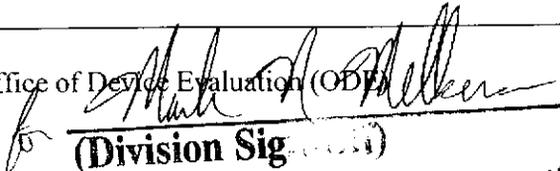
Indications: Synthes 5.0/7.3 mm Cannulated Locking Screws are intended to be used with existing Synthes LCP® plating systems for the fixation of various long bones, such as the femur.

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE) 

(Division Signature)

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