MAR 2 1 2002

K014197

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3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Matthew M. Hull (610) 647-9700 ext. 7191
Name of the Device	Synthes High Tibial Osteotomy Plate
Device Classification(s)	Class II, §888.3030 – Plate, Fixation, Bone
Substantial Equivalence	Documentation was provided which demonstrated the Synthes High Tibial Osteotomy Plate to be substantially equivalent to another legally marketed device.
Device Description	The Synthes High Tibial Osteotomy Plate is a flat, triangle shaped metal plate, that works as a tension band utilizing traditional internal plate/screw fixation.
Indications	The Synthes High Tibial Osteotomy Plate is intended for closing wedge high tibial osteotomies for treatment of bone and joint deformities and misalignment caused by injury or disease such as osteoarthritis.
Material	Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Matthew M. Hull, RAC
Senior Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, PA 19301

Re: K014197
Trade/Device Name: Synthes High Tibial Osteotomy Plate
Regulation Number: 21 CFR §888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 19, 2001
Received: December 21, 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" (21 CFR 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,

for Mark N Melkerson

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): K014197

Device Name: Synthes High Tibial Osteotomy Plate

Indications for Use:

The Synthes High Tibial Osteotomy Plate is intended for closing wedge high tibial osteotomies for treatment of bone and joint deformities and misalignment caused by injury or disease such as osteoarthritis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_

for Mark N Milhran
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014197