K000972

JUN 1 6 2000

14. Summary of Safety and Effectiveness Information:

510(k) SUMMARY

Submitter	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Bonnie Smith (610) 647-9700
Name of the Device	Synthes (USA) Trochanter Stabilization Plate for DHS®
Common or Usual Name	Single/multiple component metallic bone fixation appliance
Predicate Device	Synthes (USA) Dynamic Hip Screw (DHS®) plating system
Device Description	The Synthes Trochanter Stabilization Plate for DHS is a component of the Synthes DHS System, which fits over the sideplate of the DHS. The spoon-shaped area of the TSP, which is proximal to the shaft, resides along the greater trochanter. Screw holes of the TSP shaft line up with the screw holes of the DHS plate to accept the 4.5 mm cortex screws used for fixation to the femoral shaft. Two screw slots accommodate the DHS lag screw and the anti-rotational screw located proximal to it. Synthes Trochanter Stabilization Plates are provided both pre-sterilized by gamma radiation and nonsterile.
Intended Use	The Synthes Trochanter Stabilization Plate (TSP) for DHS is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the Synthes Dynamic Hip Screw (DHS) plating system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 6 2000

Ms. Bonnie J. Smith, RAC
Senior Regulatory Affairs Associate
SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301

Re: K000972
Trade Name: Synthes Trochanter Stabilization Plate for DHS®
Regulatory Class: II
Product Code: LXT
Dated: March 24, 2000
Received: March 27, 2000

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Premarket Notification [510(k)]

INTENDED USE STATEMENT

510(k) Number (if known): _____

Device Name: Synthes (USA)Trochanter Stabilization Plate for DHS®

Indications

Synthes Trochanter Stabilization Plate (TSP) for DHS® is intended to treat stable and unstable intertrochanteric, subtrochanteric, pertrochanteric and basilar neck fractures when used in conjunction with the Synthes Dynamic Hip Screw System (DHS®).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000972