SYNTHES

K974537
Feb. 18, 1998

Attachment VIII: **Summary of Safety and Effectiveness Info. [510(k) Summary]**

SUBMITTER	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Sheri L. Musgnung
COMMON OR USUAL NAME:	Appliance, Fixation, Nail/Blade/Plate Combination, Single Component
DEVICE CLASSIFICATION:	Class II, 21 CFR 888.3030; 888.3040
PREDICATE DEVICE:	Synthes Cannulated Angle Blade Plate System (K954289)
DESCRIPTION:	The CABP is a straight plate with a blade at the head to allow for better fixation in the head of the humerus or in the distal tibia. The blade of the plate is cannulated to fit over a guide wire, allowing for the adjustment of the wire placement several times without adversely affecting the final result. There are cuts in the undersurface of the plate to reduce the surface area of the plate in contact with bone. The area of contact between the plate and the bone is decreased in an effort to reduce damage to the cortical blood supply under the plate, and resultant reduction in damage-induced porosis and remodeling of the bone near the plate undersurface. Plate undercuts also make the bending properties of the plate more uniform, which facilitate contouring. The plate has round and dynamic compression screw holes, accepts 4.5 mm and 6.5 mm screws, is available in multiple blade lengths, and is manufactured from stainless steel and commercially pure titanium.
INTENDED USE:	Synthes CABP System is a plate and screw system intended to treat fractures of the proximal humerus and distal tibia. Proximal humerus fractures include two-part greater tubercle fractures and fracture dislocations, two-part surgical neck fractures and fracture dislocations, three-part fractures or fracture dislocations, fractures in osteopenic bone. and nonunions and malunions. Distal tibia fractures include acute fractures, fractures in osteopenic bone, and nonunions and malunions.

1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sheri L. Musgnung
Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

FEB 18 1998

Re: K974537
Synthes (USA) Cannulated Angle Blade Plate (CABP) System
Regulatory Class: II
Product Code: KTT
Dated: December 2, 1997
Received: December 3, 1997

Dear Ms. Musgnung:

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 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 (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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

SYNTHES (USA)
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Post Office Box 1766
Paoli, Pennsylvania 19301
Telephone 610-647-9700

510(k) Number (if known): K974537

Device Name: Synthes (USA) Cannulated Angle Blade Plate System

Indications For Use:

The Synthes CABP System is a plate and screw system intended to treat fractures of the proximal humerus and distal tibia. Proximal humerus fractures include two-part greater tubercle fractures and fracture dislocations, two-part surgical neck fractures and fracture dislocations, three-part fractures or fracture dislocations, fractures in osteopenic bone, and nonunions and malunions. Distal tibia fractures include acute fractures, fractures in osteopenic bone, and nonunions and malunions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974537