JUL 29 1998

SYNTHES®

K982222

Attachment VII: **Summary of Safety and Effectiveness Information [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; Screw, Fixation, Bone
DEVICE CLASSIFICATION:	Class II, 21 CFR 888.3030 and 888.3040
PREDICATE DEVICE:	Synthes Condylar Buttress Plates
DESCRIPTION:	Synthes DFP System is a plate and screw system. The primary feature of the plate and screw system is that the 7.3 mm locking screws engage with the head of the plate to form a locked, fixed angle construct. The DFP shaft features dynamic compression unit (DCU) screw holes and a limited- contact profile. The plate is available with an anatomically curved head in the longitudinal plane of the plate. The overall length of the plate ranges from 178 mm to 322 mm. The head of the plate has six screw holes: four of the six holes are threaded to accept the 7.3 mm locking screws; the two posterior holes are non-threaded and will accept 6.5 mm cancellous screws or 7.0 / 7.3 mm cannulated screws for additional fixation. The shaft will accept 4.5 mm cortex screws. The 7.3 mm locking screws feature self-drilling and self-tapping tips, are cannulated, and are available in lengths ranging from 50 mm to 110 mm. The threads just below the head of the screw engage with the threaded holes of the DFP. This engagement of the screw to the plate creates a locked, fixed angle construct. Synthes 4.5 mm cortex screws, 6.5 mm cancellous screws, and the 7.0 mm / 7.3 mm cannulated screws can be utilized with this system as well.
INTENDED USE:	Synthes DFP System is intended for buttressing multifragmentary distal femur fractures. Distal femur fractures include supra-condylar; condylar; articular and extra-articular fractures; fractures in osteopenic bone; and acute fractures, non-unions and malunions.
MATERIAL:	Stainless steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1998

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

Re: K982222
Trade Name: Distal Femur Plate (DFP) System
Regulatory Class: II
Product Codes: HWC, HRS, HTY, and JDW
Dated: June 23, 1998
Received: June 24, 1998

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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm

inclusively, the package insert must include the following statement, **"WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K982222

Device Name: Synthes (USA) Distal Femur Plate (DFP) System

Indications For Use:

Synthes Distal Femur Plate (DFP) System is intended for buttressing multifragmentary distal femur fractures. Distal femur fractures include supra-condylar; condylar; articular and extra-articular fractures; fractures in osteopenic bone; and acute fractures, non-unions 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 K982222