2/18/99

SYNTHES®

K98 4498

Attachment VI: **Summary of Safety and Effectiveness Information [510(k) Summary]**

SUBMITTER	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
CONTACT:	Angela J. Silvestri
COMMON OR USUAL NAME:	External Fixation Frame
DEVICE CLASSIFICATION:	Class II, 21 CFR 888.3030; 888:3040
PREDICATE DEVICE:	Synthes Simple Small External Fixatior (K963618) Hand Biomechanics Lab-Agee-WristJack (K942906) Biomet Inc, Hammer Mini-Tubular External Fixation Device (K982982)
DEVICE DESCRIPTION:	The Articulating Distal Radius Fixator is a preassembled mechanically adjustable external wrist fixator. It is a one-piece construct, which consists of plastic and metal components. The device is applied to the bone with four self-drilling Schanz Screws that lock into two fixator clamps. The device is operated by turning screws, which operates gears to achieve incremental movement.
INTENDED USE:	Synthes Distal Radius Plate System is intended for fixation of the distal radius.
MATERIAL:	Polyetherimide resin, stainless steel, and Ti-6A1-4V

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K984498
Trade Name: Synthes (USA) Articulating Distal Radius Fixator
Regulatory Class: II
Product Code: KTT
Dated: December 15, 1998
Received: December 17, 1998

Dear Ms. Silvestri:

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,

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): _____

Device Name: Synthes (USA) Articulating Distal Radius Fixator

Indications For Use:

Synthes Articulating Distal Radius Fixator System is intended for stabilizing fractures of the distal radius.

(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 K984498