OCT 16 1997

SYNTHES®

K973017

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

SUBMITTER:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Kevin J. O'Connell
COMMON OR USUAL NAME:	Traction, Component, Invasive
CLASSIFICATION CODE:	21 CFR, Section: 888.3040
PREDICATE DEVICE:	Synthes Adjustable Clamp
DESCRIPTION:	The Synthes Combination Clamp and Dynamization Clip attaches the Schanz screws (pins) to an 11 mm rod or tube, or two rod/tubes together. It consists of two spring compressed opposing vise plates that are interlocked to a one piece self contained clamp. The Dynamization clip is inserted into the clamp to allow dynamization. The device is manufactured from a Titanium Alloy and Stainless Steel.
INTENDED USE:	Generally intended to be used in the construction of an external fixation frame to treat long bone and pelvic fractures. Specifically for: • stabilization of soft tissue injuries and open or closed fractures; • polytrauma; • vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures; • arthrodesis and osteotomies with soft tissue problems; • failures of total joints; • neutralization of fractures stabilized with limited internal fixation; • non-unions/septic non-unions; • intraoperative reduction/stabilization tool to assist with indirect reduction; • unilateral rectilinear bone segment transport or leg lengthening.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 1997

Mr. Kevin J. O'Connell
Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 1766

Re: K973017
Synthes (USA) Combination Clamp and Dynamization Clip
Regulatory Class: II
Product Code: KTT
Dated: August 12, 1997
Received: August 13, 1997

Dear Mr. O'Connell:

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®

510(k) Number (if known): _____

Device Name: Synthes (USA) Combination Clamp and Dynamization Clip

Indications for use:

The Synthes Combination Clamp with Dynamization Clip is generally intended to be used in the construction of an external fixation frame to treat long bone and pelvic fractures. Specifically, the Synthes Combination Clamp with Dynamization Clip is intended for:

- stabilization of soft tissue injuries and open or closed fractures;
- polytrauma;
- vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures;
- arthrodesis and osteotomies with soft tissue problems;
- failures of total joints;
- neutralization of fractures stabilized with limited internal fixation;
- non-unions/septic non-unions;
- intraoperative reduction/stabilization tool to assist with indirect reduction;
- unilateral rectilinear bone segment transport or leg lengthening;

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973017

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