K974525

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

MAR - 2 1998

SYNTHES (U.S.A.)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact: Barry E. Sands
11/6/97

Device: SYNTHES Spine Anterior Thoracolumbar Rod Clamp (ATRC) System compared to the Synthes Spine Anterior Thoracolumbar Locking Plate System (ATLP) and the Synthes Spine Universal Spinal Rod and Screw Fixation System (USS) cleared in K925351 and K922855, respectively.

The Synthes Spine Anterior Thoracolumbar Rod Clamp (ATRC) System consists of a rod, a choice of three clamps, one bone screw and one set screw. It is intended for use in stabilizing

- bone graft following anterior decompression of burst fractures.
- vertebrectomy and vertebral body replacement in tumor patients.
- anterior fusion following failed posterior lumbar surgery.
- anterior fusion following severe disc degeneration. ***Degenerative Disc Disease is defined as back pain of a discogenic origin with degeneration of the disc confirmed by history and radiographic studies.***
- correction of anterolateral kyphotic deformities for the spine, lumbar scoliosis and pseudoarthrosis of the thoracolumbar spine.

This system is intended for anterolateral intervertebral body screw fixation/attachment to the T8 - L5 spine.

The rod and set screw used in this system are identical to that of the USS. The bone screw is identical to that in the ATLP system.

The two ends of two rods, of appropriate length, are inserted into the two (unthreaded) holes of each clamp and locked into position by the set screws included in the clamps. The construct is then placed on the anterolateral aspect of the spinal segment to be stabilized. The construct is attached to the vertebral bodies by four 7.5mm self-tapping unicortical screws.

All implantable components are manufactured from either CP titanium, which conforms to ASTM Standard F67, or TAN, which conforms to ASTM F1295. The instruments used to attach the construct to the spine are made from various grades of Stainless Steel.

The Anterior Thoracolumbar Rod Clamp (ATRC) System is indicated for the same clinical indications as that of the identified legally marketed predicate systems. Material composition is identical to these systems as well. The implantable components are equivalent in terms of safety and effectiveness. In fact, the set screw and the 7.5mm bone screw (with the exception of one length) and rods are identical in design when compared to the predicate devices. The surgical technique and instrumentation to implant this system is equivalent in terms of safety and effectiveness.

This system is provided non-sterile; moist heat sterilization is recommended

Based on the above, the Synthes Spine Anterior Thoracolumbar Rod Clamp (ATRC) System is substantially equivalent to the Synthes Spine Anterior Thoracolumbar Locking Plate System (ATLP) and the Synthes Spine Universal Spinal Rod and Screw Fixation System (USS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Barry E. Sands
Manager, Regulatory Affairs
SYNTHES Spine
P. O. Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

MAR - 2 1998

Re: K974525
Anterior Thoracolumbar Rod Clamp (ATRC) System
Regulatory Class: II
Product Code: KWQ
Dated: December 1, 1997
Received: December 2, 1997

Dear Mr. Sands:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 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 your device system subject to the general controls provisions of the Act and the limitations identified below.

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 this device system for pedicular screw fixation/attachment would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, 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. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the

package insert must include the following statement, **"WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";

2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and

3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system 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 system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an 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.

FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or other manufacturers', may also be required.

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 (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

510(k) Number (if known): NA

Device Name: Synthes Spine Anterior Thoracolumbar Rod Clamp (ATRC) System

Indications for Use:

The Synthes Spine Anterior Thoracolumbar Rod Clamp (ATRC) System consists of a rod, a choice of three clamps, one bone screw and one set screw. It is intended for use in stabilizing

- bone graft following anterior decompression of burst fractures.
- vertebrectomy and vertebral body replacement in tumor patients.
- anterior fusion following failed posterior lumbar surgery.
- anterior fusion following severe disc degeneration. ***Degenerative Disc Disease is defined as back pain of a discogenic origin with degeneration of the disc confirmed by history and radiographic studies.***
- correction of anterolateral lordotic deformities for the spine, lumbar scoliosis and pseudoarthrosis of the thoracolumbar spine.

This system is intended for anterolateral intervertebral body screw fixation/attachment to the T8 - L5 spine.

(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 [illegible]
510(k) Number K974525