

AUG - 1 1997

Summary of Safety and Effectiveness Information

Synthes (USA)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact:
Barry E. Sands

Synthes Titanium Locking Plate System (TiLPS) is compared to the Synthes Anterior Cervical Vertebrae Plate System (K926453 and K945700), and the Synthes Anterior Spinal Plate System (K925351).

The Synthes TiLPS is intended for anterior intravertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease.

DDD is defined as follows: back pain of a discogenic origin with degeneration of the disc confirmed by history and radiographic studies

The system consists of a two hole locking plate, 4.35 mm expansion screws with 1.8 mm locking screws. The two hole plate is available in various lengths and is manufactured from commercially pure titanium.

The TiLPS is intended to be used as follows: The plate is placed against the anterior aspect of the vertebral body, the 4.35 mm expansion screw is inserted through the holes of the Titanium Locking Plate into the vertebral body, and tightened until the screw head is fully seated in the plate. At this point, the 1.8 mm screw with locking head is inserted into the 4.35 mm expansion screw by way of the mating threads (1.8 mm) on these parts. As the locking screw is tightened, the conical head of this screw engages the conical bore within the head of the expansion screw. In addition to the conical bore, the head of the expansion screw is slotted so that further tightening of the locking screw serves to expand the four sections of the expansion screw head outward. This outward (radial) expansion of the 4.35 mm expansion screw head creates locking force between the screw and plate. Implant removal is accomplished in reverse order.

The TiLPS is similar in plate width, thickness and length to the Anterior Cervical Vertebrae Plate System and is manufactured from the same material. The plate attaches to the bone through the use of an expansion screw with a locking screw.

Based on this information, Synthes Titanium Locking Plate System is substantially equivalent to Synthes Anterior Cervical Vertebrae Plate System and Synthes Anterior Spinal Plate System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Re: K970048
Trade Name: Synthes Titanium Locking
Plate System
Regulatory Class: II
Product Code: KWQ
Dated: May 5, 1997
Received: May 7, 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.

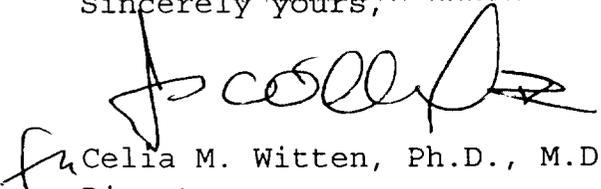
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,



fu 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



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510(k) Number (if known): K970048

Device Name: Synthes (USA) Titanium Locking Plate System

Indications for Use:

The Synthes TiLPS is intended for anterior intravertebral body screw fixation/attachment to the L1-S1 spine over one vertebral body extending onto the adjacent intervertebral space. Due to variations in the anatomy, the plate is designed for applications caudal to the bifurcation of the great vessels. Specifically, the device is intended for stabilization and buttressing of bone graft over one motion segment following anterior structural reconstruction for degenerative disc disease.

DDD is defined as follows: back pain of a discogenic origin with degeneration of the disc confirmed by history and radiographic studies

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970048