

C.

NOV 25 1998

K982322  
**Summary of Safety and Effectiveness Information**  
**[510(k) Summary]**

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

(610) 647-9700  
 Contact: Jonathan M. Gilbert  
 9/4/98

Device: Synthes Spine Occipital-Cervical Plate/Rod and Hook System compared to the Ransford Cervical Fixation System (K965221).

The Synthes Spine Occipital-Cervical Plate/Rod and Hook System consists of plate/rod, hooks, set screws and bone screws for the occipital region of the skull. The plate/rods, hooks, and set screws are manufactured from the titanium alloy TiAlNb (ASTM F1295). The bone screws are manufactured from commercially pure titanium Grade 4 (ASTM F67). The Occipital-Cervical Plate/Rod and Hook System is intended to provide stabilization to promote fusion of the occipital-cervical junction (occiput-T3) for the following indications:

- Degenerative disc disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis of the cervical vertebrae
- Spinal stenosis of the cervical vertebrae
- Atlanto-axial fracture with instability
- Occipital-cervical dislocation
- Revision of cervical spine fusion surgeries
- Tumors

The plate/rod is a 3.5 mm or 6.0 mm diameter rod that transitions into a 3.5mm reconstruction plate at the opposite end. The plate/rod is bent and cut to an appropriate length. The plate portion of the implant is fixed to the occiput with screws and the rod portion is attached to the cervical spine with hooks. Hooks are available in both right and left opening configurations to allow bilateral placement of the hook/rod construct.

Manual surgical instruments that will be marketed with this system include Bending Pliers for 3.5 rods, a 2.5mm Hex screwdriver and holding forceps.

Mechanical testing was performed in accordance with ASTM standard F1717. This testing documented both static and fatigue performance characteristics. This testing and previous evaluation clearly demonstrated that the performance characteristics satisfy the requirements of posterior cervical and upper thoracic (T1-T3) fixation.

The Synthes Spine Occipital-Cervical Plate/Rod and Hook System is indicated for the same clinical indications as that of the Ransford Cervical Fixation System (K965221).

Material composition is identical to numerous other Synthes Spinal products that have been cleared via the 510(k) process. The surgical technique and instrumentation to implant this system is the same as that of the Synthes USS Hook/Rod systems.

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

Based on the above, the Synthes Spine Occipital-Cervical Plate/Rod and Hook System is substantially equivalent to the Ransford Cervical Fixation System (K965221).



NOV 25 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jonathan M. Gilbert  
Senior Regulatory Affairs Associate  
Synthes Spine  
1690 Russell Road  
Paoli, Pennsylvania 19301

Re: K982322  
Trade Name: Occipital-Cervical Plate/Rod and Hook System  
Regulatory Class: II  
Product Code: KWP  
Dated: September 4, 1998  
Received: September 8, 1998

Dear Mr. Gilbert:

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.

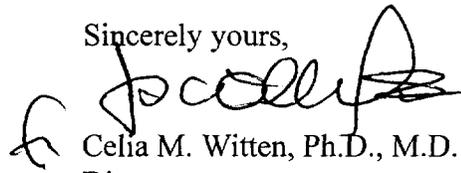
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Jonathan M. Gilbert

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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

A.

### Intended Use Form

Page 1 of 1

510(k) Number (if known): **K982322**

Device Name: Synthes Spine Occipital-Cervical Plate/Rod and Hook System

Indications for Use:

The Synthes Spine Occipital-Cervical Plate/Rod and Hook System is intended to provide stabilization to promote fusion of the cervical spine and occipital-cervical junction (occiput - T3) for the following indications:

- Degenerative disc disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis of the cervical vertebrae
- Spinal stenosis of the cervical vertebrae
- Atlanto-axial fracture with instability
- Occipital-cervical dislocation
- Revision of cervical spine fusion surgeries
- Tumors

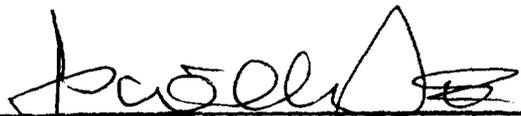
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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   K982322