3/30/99

Attachment 7

K990708

510(k) Summary

Summary

Company: Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
Date: March 3, 1999
Trade Name: Titanium Versalok Screw Assembly
Common Name: Spondylolisthesis Spinal Fixation Device System
Predicate Device: Versalok Screw Assembly

Description/Intended Use: The Titanium Versalok Screw Assembly consists of straight rods, an outer ring, cap, and polyaxial screws, and the instruments necessary to implant this specific system. The Titanium Versalok Screw Assembly is intended to provide stabilization of the spine for various indications (see below). The device is intended to be removed after solid fusion has occurred.

A construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used only for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint (see warnings below). The device is intended to be implanted using a posterior surgical approach and removed after the development of a solid fusion mass.

When not used as a pedicle screw fixation system, various combinations of the Titanium Versalok Screw Assembly components are also indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1) during bony fusion healing secondary to:

1. Unstable spinal fractures (such as fracture dislocations) or instability secondary to spinal tumors;
2. Degenerative disk diseases of the spine (defined as back pain of diskogenic origin with degeneration of the disk confirmed by radiographic studies);
3. Spinal curvatures (such as idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, and secondary to spinal fractures) which are:
    - Progressive, despite other forms of treatment,
    - Detrimental to cardiopulmonary function,
    - Interfering with spinal mechanics or causing severe back pain, or
    - Cosmetically unacceptable, progressive, and painful.

The system is intended to provide temporary maintenance and support of the correction during the time normally needed for the fusion mass to mature. Use of spinal fixation instrumentation in children has been reported. Children should have adequate bony and soft tissue maturity to undergo implantation but need not have reached skeletal maturity.

The Titanium Versalok Screw Assembly was declared substantially equivalent to other predicate or preamendment devices. Mechanical test data was provided in the application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 1999

Mr. Dan Regan
Director, Clinical and Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K990708
Trade Name: Titanium Versalok Screw Assembly
Regulatory Class: II
Product Codes: KWP and MNH
Dated: March 3, 1999
Received: March 4, 1999

Dear Mr. Regan:

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

Attachment 3

Indications for Use Statement

510(k) Number
(if known)

Device Name Titanium Versalok

Indications for Use

A construct with screws attached to the pedicles of the lumbar and sacral spine (L3 to S1) and autogenous bone graft may be used only for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint (see warnings below). The device is intended to be implanted using a posterior surgical approach and removed after the development of a solid fusion mass.

When not used as a pedicle screw fixation system, various combinations of the Titanium Versalok Screw Assembly components are also indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1) during bony fusion healing secondary to:

1. Unstable spinal fractures (such as fracture dislocations) or instability secondary to spinal tumors;
2. Degenerative disk diseases of the spine (defined as back pain of diskogenic origin with degeneration of the disk confirmed by radiographic studies);
3. Spinal curvatures (such as idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, and secondary to spinal fractures) which are:
   - Progressive, despite other forms of treatment,
   - Detrimental to cardiopulmonary function,
   - Interfering with spinal mechanics or causing severe back pain, or
   - Cosmetically unacceptable, progressive, and painful.

The system is intended to provide temporary maintenance and support of the correction during the time normally needed for the fusion mass to mature. Use of spinal fixation instrumentation in children has been reported. Children should have adequate bony and soft tissue maturity to undergo implantation but need not have reached skeletal maturity.

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 K990708

Prescription Use X (per 21 CFR 801.109) OR Over-The Counter Use ____