APR 29 1998

K981274

TiMX Plate Based Low Back System

510(k) SUMMARY

COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME: TiMX Plate Based Low Back System

CLASSIFICATION: Unclassified, preamendment device system

DESCRIPTION:

The TiMX Plate Based Low Back System is a variation of the existing titanium alloy VSP Spinal System previously cleared under K944736. The TiMX Plate Based Low Back System is a construct that consists of pedicle and sacral screws, spine plates, nuts, washers and a transverse connector. This modified system provides increased pedicle screw strength, increased construct fatigue performance, increased construct stiffness, improved geometry and lower profile than its predecessor, the titanium alloy VSP Spinal System.

TiMX Pedicle Screws

TiMX Pedicle Screws are made from implant grade titanium alloy conforming to ASTM F-136 specifications. The TiMX Pedicle Screw is a variation of the existing titanium alloy pedicle screw previously cleared for the VSP Spinal System under K944736.

The machine thread portion of the TiMx pedicle screws are available in two thread lengths: Standard (30.0 mm) and No Cut "+5" (17.0 mm). The No Cut "+5" machine thread requires no cutting when the screw is used with a TiMx Spine Plate and Washer. Both the Standard and No Cut "+5" thread length TiMx Pedicle screws are available in four cancellous diameters: 5.50 mm, 6.25 mm, 7.00 mm, and 7.75 mm. The larger size pedicle screws, 7.00 mm and 7.75 mm, may also be used in the sacrum. The cancellous portion of the Standard thread length is available in seven lengths that range from 25 mm to 55 mm in five millimeter increments. The cancellous portion of the No Cut "+5" thread length is also available in seven lengths that range from 30 mm to 60 mm in five millimeter increments.

TiMx Sacral Screws

TiMX Sacral Screws are made from implant grade titanium alloy conforming to ASTM F-136 specifications. The TiMX Sacral Screw is a variation of the existing titanium alloy sacral screw previously cleared for the VSP Spinal System under K944736.

The TiMX Sacral Screw is designed with a larger diameter, 8.5 mm, for placement into the sacrum. TiMX Sacral Screws are available in the No Cut "+5" (17.0 mm) machine thread length only. The No Cut "+5" machine thread requires no cutting when the screw is used with a TiMX Spine Plate and Washer. The cancellous portion is available in four lengths that range from 35 mm to 50 mm in five millimeter increments.

TiMX Spine Plates

TiMX Spine Plates are manufactured from implant grade titanium alloy conforming to ASTM F-136 specifications. The TiMX Spine Plate design is a variation of titanium alloy VSP Spine Plates previously cleared for the VSP Spinal System under K951116. The spine plate contains a series of elongated slots along the length of the plate that facilitate the longitudinal positioning of the plate. A series of overlapping nests is machines into the upper surface of the plate, producing a nested appearance in each slot. The nests prevent movement between the plate and the TiMX spherical nut when tightened. The slots, with their machine tapered nests, offer the possibility of accurate yet variable screw placement. All corners and angles on the spine plates are rounded and smoothed to reduce potential stress concentrations.

The spine plates have between one and three slots each, with their length increasing by half slot increments. Plate lengths vary from 31 mm for the shortened One Slot Plate to 138.4 mm for the 3.5A Slot Plate. All plates are 5.3 mm thick and "A" series TiMX plates are 13.0 mm wide.

TiMX Washers

TiMX Washers are manufactured from implant grade titanium alloy conforming to ASTM F-136 specifications. The TiMX Washer design is a variation of titanium alloy VSP Washers previously cleared for the VSP Spinal System under K944736. Washers are available in two styles: flat and tapered. Flat washers come in three sizes, 3 mm, 4.50mm and 5.0 mm. All edges of the washers are rounded. All washers have a chamfered inner hole for placement on the machine threaded portion of the TiMX screws. The tapered washer comes in one size with two different shaped inner holes: one round and the other oblong.

The flat washer is used to elevate the plates above the flat surface of the pedicle screw's integral nut. The washer provides a flat surface for the plate to rest upon, reducing bending stress placed on the screw. It corrects for the uneven topography of the surgically prepared bone bed, permits facet joint clearance, and creates more space under the plate for bone graft packing (aka the posterolateral fusion).

TiMX Transverse Connector

TiMX Transverse Connector is manufactured from implant grade titanium alloy conforming to ASTM F-136 specifications. The TiMX Connector design is a variation of titanium alloy VSP Transverse Connector previously cleared for the VSP Spinal System under K944736. The connector has three components: one left connector assembly, one right connector assembly and one rod. Each connector assembly has two parts: a body and a set screw. The rod is available in 1 diameter: 4.75mm, 100 mm long.

MATERIAL:

The Implant components of the TiMX Plate Based Low Back System are all manufactured from implant grade titanium alloy conforming to ASTM F-136 specifications.

INDICATIONS:

The Titanium MX Plate Based Low Back System is intended for use in Grade 3 and 4 spondylolisthesis at L5-S1, when affixed to the lumbosacral spine, utilizing autologous bone graft, and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum.

PERFORMANCE DATA:

Statistical analysis of the results of static and fatigue component testing of the TiMX Pedicle Screw showed significant improvement of the TiMX design in torque plus bending with the VSP plates, better torque to failure performance of the hexlobe feature and 30% improvement in endurance limit of the TiMX design compared to standard titanium VSP pedicle screws.

A full battery of testing which consisted of static compression bending, static torsion, and dynamic compression bending was performed on both the TiMX and standard titanium VSP systems. These test results have shown the TiMX plate system is generally superior or equivalent to the previously cleared components of the standard titanium VSP system.

SUBSTANTIAL EQUIVALENCE:

The TiMX Low Back System is equivalent to AcroMed's Titanium VSP Spinal Fixation System as cleared under K944736 and to the Harrington System, manufactured by Zimmer beginning in the 1960s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1998

Ms. Mary Lewis
Product Approval Partner
AcroMed Corporation
3303 Carnegie Avenue
Cleveland, Ohio 44115

Re: K981274
TiMX Plate Based Low Back System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: April 6, 1998
Received: April 8, 1998

Dear Ms. Lewis:

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). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. 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 for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is 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. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

   WARNINGS:

   - When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.

   - The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.

   - Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

   - Potential risks identified with the use of this device system, which may require additional surgery, include:

     device component fracture,
     loss of fixation,
     non-union,
     fracture of the vertebra,
     neurological injury, and
     vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device 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 for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

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 your device system 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 those of 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): K981274

Device Name: AcroMed TiMX Low Back System

Indications for Use:

The Titanium MX Low Back System is intended for use in Grade 3 and 4 spondylolisthesis at L5-S1, when affixed to the lumbosacral spine, utilizing autologous bone graft, and intended to be removed after solid fusion is attained.

Levels of attachment for this indication range from L3 to the sacrum.

(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 K981274

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

(Optional Format 1-2-96)