JUN 30 1998

TiMX Low Back System K981714

510(k) SUMMARY
of the rod-based version of the TiMX Low Back System

COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME:

TiMX Low Back System

CLASSIFICATION:

For Pedicle Screw Use:
Unclassified- Spondylolisthesis Spinal Fixation Device System

For Non-Pedicle Screw Use:
Spinal Interlaminal Fixation Orthosis

DESCRIPTION:

All components of the TiMX Low Back System are made from implant grade titanium alloy conforming to ASTM F-136 specifications. TiMX pedicle and sacral screws, TiMX washers, TiMX slotted and cross connectors and TiMX Twister connectors are used in conjunction with the Isola System titanium components to comprise a rod based spinal fixation 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 Isola Spinal System under K952236 and is the same screw that was found substantially equivalent for use with plates in K981274.

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. Both the Standard and No Cut +5 thread length TiMX

DESCRIPTION:
(Continued)

TiMX Pedicle Screws

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 Isola Spinal System under K952236 and is the same screw that was found substantially equivalent for use with plates in K981274.

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. The cancellous portion is available in four lengths that range from 35 mm to 50 mm in five millimeter increments.

TiMX Washers

TiMX Washers are manufactured from implant grade titanium alloy conforming to ASTM F-136 specifications. The TiMX Washer design is the same as previously cleared for the TiMX Low Back System under K981274. 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.

DESCRIPTION:
Continued

TiMX Rod Based Slotted and Cross Connectors

TiMX Connectors are manufactured from implant grade titanium alloy conforming to ASTM F-136 specifications. The Modular Cross Connector utilizes J-hooks which can be positioned anywhere along the construct to provide rod to rod connection. The TiMX Connector designs are a variation of titanium alloy Isola Slotted Connectors and the Modular Cross Connector and J-Hooks previously cleared for the Isola Spinal System under K952236.

The TiMX slotted connector assembly has two parts: a body and a set screw. Slotted connectors provide screw-to-connector-to-rod union. Slotted and offset designs are available in ¼ inch diameters to accommodate the rod size. The slotted portion of each connector provides surgical latitude for screw placement. The machine threaded portion of the connector is locked to the screw with the nut. The rod is locked to the connector with the hexlobe set screw. The TiMX slotted connectors are offered in five designs: straight and extended (each with a 90° angle at the rod locking end), angled (with a 45° angle), offset left, and offset right.

TiMX Twister Connector

TiMX Twister Connector is manufactured from titanium alloy conforming to ASTM F-136 specifications. The TiMX Twister Connector is a variation of the titanium alloy Isola Twister Connector previously cleared for the Isola Spinal System under K965046.

The Twister Connector, like other slotted connectors, provides a stable, strong and durable screw-to-connector-to -rod union. To provide secure fixation to the rod, a patented V-Groove Hollow Ground (VHG) design is used in all connectors. The two piece Twister connector design utilizes the attributes of the one piece connectors. It consists of a slotted transverse member with splines which mate with the splines of the V-Groove body. Together these two pieces create the slotted connector assembly. The spline connection or joint is the medium by which the screw/connector interface can be manipulated and secured. This two piece design allows for intraoperative sagittal alignment in 7° increments.

MATERIAL:

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

INDICATIONS:

When labeled for pedicle screw fixation, the TiMX 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.

When labeled for non-pedicle screw posterior fixation, the TiMX Low Back System is intended for hook, wire and/or sacral/iliac screw fixation from the thoracic spine to the ilium/sacrum. Properly used, the posterior TiMX Low Back System will provide temporary stabilization as an adjunct to spinal bone grafting process. Specific indications are:

1. Idiopathic scoliosis.
2. Neuromuscular scoliosis/ kyphoscoliosis with associated paralysis or spasticity.
3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.
4. Spinal fractures (acute reduction or late deformity).
5. Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).
6. Spondylolisthesis.
7. Neoplastic disease.
8. Previous Failed Fusion.

Levels of attachment for these indications range from T1 to the sacrum. This system is intended for single use.

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 was conducted on titanium constructs which included static tests in compression bending and torsion, and fatigue tests in compression bending. Fatigue test results have indicated that the TiMX Low Back System has a significantly higher endurance limit than the standard titanium Isola system. Static and dynamic compressive bending tests have shown that the TiMX Low Back System constructs have equal or superior mechanical properties when compared to standard titanium Isola constructs. Static torsion testing showed a lower torsional stiffness and similar torsional strengths for the TiMX Low Back System compared to the titanium standard Isola system.

Additional full battery of testing was undertaken to characterize the TiMX Low Back System with TiMX Twister constructs. Fatigue test results have indicated that the TiMX Low Back System with four Twister connectors had an endurance limit of 250N. The static bending strength of the constructs was 755.8N with a bending stiffness of 23.1N/mm. The torsional strength was 38.4N with a stiffness of 5.5Nm/deg.

SUBSTANTIAL EQUIVALENCE:

The TiMX Low Back System is a variation of and substantially equivalent to AcroMed's titanium alloy Isola Spinal Fixation System as previously cleared under K952236 and to the Harrington System, manufactured by Zimmer beginning in the 1960's.

The TiMX Twister Connector is a component of the rod based version of the TiMX Low Back System and is a variation of the existing titanium alloy Isola Twister Connector previously cleared under K965046.

The TiMX Low Back System Pedicle and Sacral screws are variations of the existing titanium alloy pedicle and sacral screws previously cleared for the Isola Spinal System under K952236 and are the same screws that were found substantially equivalent for use with plates in K981274.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

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

Re: K981714
TiMX Plate Based Low Back System (rod-based version)
Regulatory Class: II
Product Codes: KWP and MNH
Dated: May 14, 1998
Received: May 15, 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

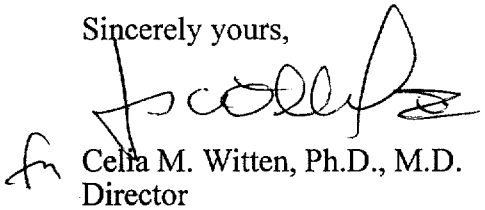
not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

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

Sincerely yours,



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): K981714 (Under Review)

Device Name: AcroMed TiMX Low Back System (rod-based components)

Indications for Use:

When labeled for pedicle screw fixation, the TiMX 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.

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8. Previous Failed Fusion.

Levels of attachment for these indications range from T1 to the sacrum. This system is intended for single use.

(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 K981714

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

(Optional Format 1-2-96)