

K980228

AcroMed
University^{AM} PlateTM Anterior System
510(k) SUMMARY

COMPANY: AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME: University^{AM} PlateTM Anterior System

CLASSIFICATION: Spinal Intervertebral Body Fixation Orthosis
Class II

DESCRIPTION:

University^{AM} PlateTM Anterior System Plates: The University^{AM} PlateTM Anterior System plates are fabricated from ASTM F-136 implant grade titanium alloy. The plates have a contoured low profile to match the curvature of the lateral aspect of the thoracolumbar vertebral bodies. The slot pattern allows a wide range of screws and bolt placement, while the spherical countersinks allow up to 15 degrees of screw angulation. The University^{AM} PlateTM Anterior System plates are either rectangular or distally tapered, and come in a variety of lengths. Distally tapered plates are used at the L4 level to allow the common iliac vessels to cross without undue pressure.

The University^{AM} PlateTM Anterior System Bolts and Screws: The University^{AM} PlateTM Anterior System screws are fabricated from ASTM F-136 implant grade titanium alloy. Bolts are 7.0mm in diameter and screws are 6.25mm in diameter. Bolts and screws are available in 5mm length increments. When inserted, the tip of each bolt or screw should extend one thread through the opposite cortex of the vertebra to increase holding power.

The University^{AM} PlateTM Anterior System Drill Guide: The University^{AM} PlateTM Anterior System Drill guide is designed to allow precise drilling of the vertebral bodies and to act as a sizing template for the plates. Serious vascular or neurological complications may occur if the drill guide is not used. (See Precautions).

MATERIAL: The components of the University^{AM} PlateTM Anterior System are manufactured from titanium alloy conforming to ASTM F-136 specifications.

INDICATIONS: The University^{AM} PlateTM Anterior System is intended for lateral screw fixation to the T9-L4 levels of the spine, and is not suitable for attachment to the sacrum. Specific indications are fracture, tumor, previous failed fusion and pseudoarthrosis, and degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).

PERFORMANCE DATA: Static and fatigue testing show the University^{AM} PlateTM Anterior System to perform consistently with previously cleared components.

SUBSTANTIAL EQUIVALENCE: The University^{AM} PlateTM Anterior System is substantially equivalent to the CASFTM Contoured Anterior Spinal Fixation System as cleared under K904446, the Kaneda Anterior Spinal Multisegmental Fixation Device as cleared under K923703 and the ISOLA Anterior Spinal System as cleared under K943819.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William Christianson
Vice President, Regulatory Affairs
AcroMed® Corporation
3303 Carnegie Avenue
Cleveland, Ohio 44115

APR 14 1998

Re: K980228
University^{AM} PlateTM Anterior System
Regulatory Class: II
Product Code: KWQ
Dated: January 20, 1998
Received: January 22, 1998

Dear Mr. Christianson:

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 (Pre-market 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 pre-market 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 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 Stephen Rhoads
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): K980228

Device Name: University^{AM} PlateTM Anterior System

Indications for Use:

The University^{AM} PlateTM Anterior System is intended for lateral screw fixation to the T9-L4 levels of the spine, and is not suitable for attachment to the sacrum. Specific indications are fracture, tumor, previous failed fusion and pseudoarthrosis, and degenerative disc disease (defined as discogenic back pain 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 _____

(Optional Format 1-2-96)

Stephen Rhoads
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980228