

**M-2 ANTERIOR PLATE SYSTEM**

510(k) Summary

**COMPANY:** AcroMed Corporation  
3303 Carnegie Avenue  
Cleveland, Ohio 44115

OCT - 1 1997

**TRADE NAME:** M-2 Anterior Plate System

**CLASSIFICATION:** Spinal Intervertebral body fixation orthosis. Class II

**DESCRIPTION:** The M-2 Anterior Plate System is a construct which consists of one M-2 plate attached to the vertebral body by either four M-2 screws or by two M-2 screws and two M-2 bolts. Surgeon preference dictates which type of implant construct is utilized. The components of the M-2 Anterior Plate System have been designed with anatomic limitations in mind.

**M-2 PLATES:**

The M-2 plate is made from ASTM F-136 implant grade titanium alloy. The plate is contoured in two planes to provide a more suitable fit of the thoracic, thoracolumbar and lumbar segments of the spine. Each plate has two sets of nested slots on each end of the M-2 plate. Larger sized M-2 plates contain an additional nested slot centered in the middle of the M-2 plate for graft fixation. Each nested slot allows 15 degrees angulation of a M-2 screw. The letters A and P are etched on the M-2 plate to identify the anterior and posterior portions of the M-2 plate. On the underside beneath the posterior nested slots is a machined groove designed to prevent rotation of the M-2 bolt.

M-2 plates are available in six sizes that range from 40mm to 90mm in ten millimeter increments.

**M-2 SCREWS:**

The M-2 screw is made from ASTM F-136 implant grade titanium alloy. The M-2 screw has a cancellous diameter of 4.75mm. The M-2 screw is capable of 15 degrees angulation within each nested slot of the M-2 plate. A M-2 screw may be used in all nested slots of the M-2 plate.

The 4.75mm diameter M-2 screws are available in seven lengths which range from 25mm to 55mm in five millimeter increments.

#### M-2 BOLTS:

The M-2 bolt and spherical nut are made from ASTM F-136 implant grade titanium alloy. The M-2 bolt is composed of two parts: a long cancellous section with an integral fixed lower nut and a machine threaded section above the integral nut. A spherical nut secures the M-2 bolt to the M-2 plate. M-2 bolts have a threaded cancellous of 5.50mm. The integral nut portion of the M-2 bolt connects into the machined groove beneath the posterior nested slots of the M-2 plate. A bolt may be used only in the inferior and superior posterior nested slots of the M-2 plate.

The M-2 bolts are available in seven lengths that range from 25mm to 55mm in five millimeter increments.

#### PERFORMANCE DATA:

##### Non-Clinical:

Static compression bending and torsion were performed on the M-2 screw and screw/bolt constructs to characterize the properties of stiffness, strength, and maximum applied moment (torque). Dynamic bending compression testing was also performed to characterize fatigue life.

#### INTENDED USE:

The M-2 Anterior Plate System is intended for use in:

1. Degenerative Disc Disease defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.
2. Pseudoarthrosis
3. Spondylolysis
4. Spondylolisthesis
5. Burst fractures/ trauma
6. Tumor
7. Anterior fusion following failed posterior operations
8. Unsuccessful previous anterior surgery
9. Lordotic deformities of the spine

#### SUBSTANTIAL EQUIVALENCY:

Z-Plate Anterior Fixation System



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Gregory D. Cannedy  
Regulatory Affairs  
AcroMed Corporation  
3303 Carnegie Avenue  
Cleveland, Ohio 44115

OCT - 1 1997

Re: K972718  
M-2 Anterior Plate System  
Regulatory Class: II  
Product Code: KWQ  
Dated: July 16, 1997  
Received: July 21, 1997

Dear Mr. Cannedy:

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 (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.

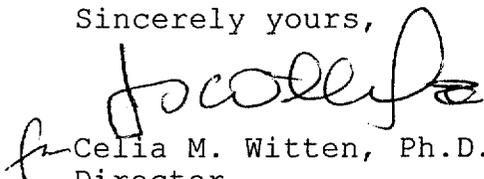
FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical 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.

Page 3 - Mr. Gregory D. Cannedy

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,



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): K972718

Device Name: M-2 Anterior Plate System

**Indications for Use:**

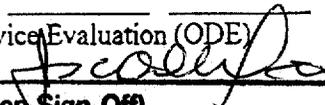
The M-2 Anterior Plate System is intended for use in:

1. Degenerative Disc Disease defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.
2. Pseudoarthrosis
3. Spondylolysis
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5. Burst fractures/ trauma
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7. Anterior fusion following failed posterior operations
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9. Lordotic deformities of the spine

The intended levels for treatment with the M-2 Anterior Plate System are T3 to L3. In order to treat levels T3 to L3, plate attachment is from T2 to L4. The M-2 Plate System is intended to treat one motion segment per construct.

(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 K972718

Prescription Use X  
(per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)