K971248

June 11, 1997

AcroMed

Kaneda Anterior Spinal System

510(k) SUMMARY

COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME:

Kaneda SR Anterior Spinal System

CLASSIFICATION:

Spinal Intervertebral Body Fixation Orthosis
Class II

DESCRIPTION:

The components of the Kaneda SR Anterior Spinal System consist of spinal plates, anterior veterbral body screws, transverse rod couplers and rods. This system can also be used in conjunction with some components of the Isola Spine System. Specifically, 1) the Isola ¼" rods 2) the Isola Open Caps and 3) the Isola Set Screws. The contoured spiked plates are designed to help the construct anchors resist axial forces and serve as a guide for placement of the screws. The plates are available in three sizes (small, medium and large) and are designed as pairs with specific caudal and rostral components. The screws serve to anchor the vertebral bodies to the longitudinal rods. The screws are available in open and closed formats designed to fit the 1/4" rod in cancellous lengths of 35 mm to 60 mm. The Kaneda Anterior Spinal System utilizes the 1/4" diameter rod, available in 18" lengths or in precut lengths from 45 mm to 150 mm.

MATERIAL:

The components of the Kaneda SR Anterior Spine System are manufactured from titanium alloy conforming to ASTM F 136 specifications.

INDICATIONS:

The Kaneda SR Anterior Spinal System is intended for anterolateral screw fixation to the T10-L3 levels of the spine, with all metal at least 1 cm. from a major vessel. Specific indications are degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, kyphosis, lordosis), tumor, fracture and revision of previous surgery.

PERFORMANCE DATA:

Static and fatigue testing show the Kaneda SR Anterior Spinal System to perform consistently with previously cleared components.

SUBSTANTIAL EQUIVALENCE:

The Kaneda SR Anterior Spinal System is substantially equivalent to the Kaneda Anterior Spinal Instrumentation as cleared under K873826, the Kaneda Anterior Spinal Multisegmental Fixation Device as cleared under K923703 and the ISOLA Anterior Spinal System as cleared under K943819.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

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

Re: K971248
Kaneda SR Anterior Spinal System
Regulatory Class: II
Product Code: KWQ
Dated: April 2, 1997
Received: April 3, 1997

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.

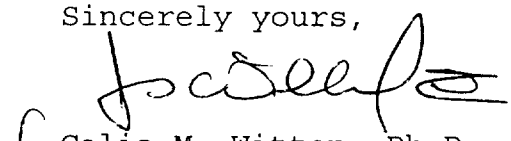
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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): K971248

Device Name: **Kaneda SR Anterior Spinal System**

Indications for Use:

The Kaneda SR Anterior Spinal System is intended for anterolateral screw fixation to the T10-L3 levels of the spine, with all metal at least 1 cm. from a major vessel. Specific indications are degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, kyphosis, lordosis), tumor, fracture and revision of previous surgery. The Kaneda system is used in conjunction with the Isola Spine System. Specifically, the 1) Isola ¼" Rods 2) Isola Open Caps and 3) the Isola Set Screws are interchangeable parts.

(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 K971248

Prescription Use X OR Over-The-Counter Use _____
(per 21 CRF 801.109)

(Optional Format 1-2-96)