

KANEDA ANTERIOR SPINAL SYSTEM

510(k) Summary

MAR - 5 1998

COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, Ohio 44115

TRADE NAME:

Kaneda Anterior Spinal System (KASS)

CLASSIFICATION:

Spinal Intervertebral body fixation orthosis. Class II

DESCRIPTION:

The Kaneda Anterior Scoliosis System is a construct that consists of two spinal staples, KASS blunt tip open and closed screws, standard Isola open and closed screws and 3/16 inch diameter Isola spinal rods.

KASS Spinal Staple:

The KASS spinal staple is made from ASTM F-138 implant grade stainless steel. The KASS spinal staple is available in a single or two-hole design.

The single hole KASS spinal staple is intended to be utilized in the thoracic spine, specifically when the anatomy of the spine restricts the use of a two-holed spinal staple. The single hole KASS spinal staple contains a centered single machined hole designed to accommodate a 6.25mm open or closed screw. The single hole KASS spinal staple is contoured in two planes. This design provides a more suitable fit when utilized in the thoracic spine. The single hole KASS spinal staple is available in one size.

The two-hole KASS spinal staple contains two machined holes placed diagonally across from one another. Both holes are designed to accommodate a 6.25mm open or closed screw. The two-hole KASS spinal staple is contoured in one plane which compliments the vertebral anatomy. The two-hole KASS spinal staple is etched with a "①" or "②" indicating the correct alignment of the spinal staples within a construct. In addition, a directional arrow (→) with the word "APEX" is etched on the two-holed KASS spinal staple. These etchings aid in the correct positioning of the two-hole spinal staple to ensure that the shortest spinal rod is posteriorly positioned in the construct. The two-hole KASS spinal staple is available in small, medium and large sizes.

Both the single and two-holed spinal staple are etched with an "A" for anterior placement and a "P" for posterior placement to the vertebral anatomy. All spinal staples are designed with four tetra-spikes on the underneath side of the staple.

Spinal Screws:

The KASS and Isola standard screws are made from ASTM F-138 implant grade stainless steel. The KASS and Isola standard screws have a cancellous diameter of 6.25mm and connect to a 3/16 (4.75mm) diameter Isola spinal rod. The spinal screws are available in two designs. A standard Isola open and closed design and a KASS open and closed screw containing a blunt tip at the end of the cancellous portion of the screw. The KASS screw is intended for bi-cortical purchase of the vertebral body.

The closed KASS and standard Isola screws are designed to thread the spinal rod through the closed screw head. The open KASS and standard Isola screws are designed with a removable cap which allows the rod to be placed into the open screw head. The cap is re-applied to the head of the open screw capturing the spinal rod. Both the open and closed design KASS and standard Isola screws utilize a Isola set screw that tightens the spinal rod into the KASS screw.

The 6.25mm diameter KASS open and closed screws are available in twelve lengths which range from 25mm to 60mm in varying millimeter increments. The 6.25mm diameter standard Isola open and closed KASS screws are available in eleven lengths which range from 20mm to 70mm in 5 millimeter increments.

Spinal Rod:

The Isola spinal rod is made from ASTM F-138 implant grade stainless steel. The spinal rod is 3/16 inch (4.75mm) diameter and has a smooth surface. The spinal rod is cut to the required length needed for the KASS construct. The spinal rod is available in a 18 and 24mm length.

PERFORMANCE DATA:

Non-Clinical:

Mechanical characterization of the 3/16 inch Kaneda Anterior Scoliosis System is tested for the following mechanical testing modes:

Static compressive bending

Static torsion

Compressive Bending Fatigue

INTENDED USE:

The Kaneda Anterior Spinal System is intended for use in:

1. Idiopathic scoliosis.
2. Degenerative Disc Disease defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.
3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.
4. Neuromuscular scoliosis/kyphoscoliosis
5. Spinal fractures (acute reduction or late deformity).
6. Revision surgery.
7. Tumor.

In addition, the Kaneda Anterior Scoliosis System can also be used for the correction and stabilization of scoliotic curves, for the prevention or recurrence of undesired scoliotic curves, and for the stabilization of weakened trunks. Indications for these scoliotic uses include:

1. Collapsing and unstable paralytic deformity.
2. Progressively increasing scoliosis.
3. Decreasing cardio-respiratory function, secondary to spinal or rib deformity or collapse.
4. Inability to maintain sitting balance, necessitating the use of hands.
5. Increasing pelvic obliquity coincident with back pain or loss of sitting balance.

The intended levels for treatment with the Kaneda Anterior Scoliosis System, are T4 to L4. The Kaneda Anterior Scoliosis System is intended to treat one motion segment per section with multiple sections per construct. The Kaneda Anterior Scoliosis System has been developed to accommodate a left or right anterior approach.

**SUBSTANTIAL
EQUIVALENCY:**

Kaneda SR Anterior Spinal System



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1998

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

Re: K974757
Kaneda Anterior Scoliosis System (KASS)
Regulatory Class: II
Product Code: KWQ
Dated: December 18, 1997
Received: December 19, 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 (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.

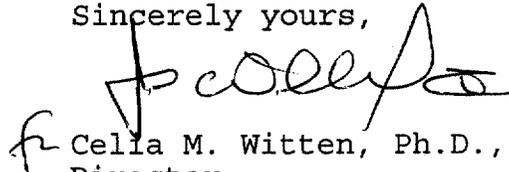
FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical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

Page 3 - Mr. Gregory D. Cannedy

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): K974757

Device Name: Kaneda Anterior Scoliosis System (KASS)

Indications for Use:

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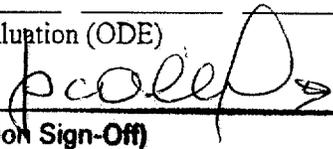
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The intended levels for treatment with the Kaneda Anterior Scoliosis System, are T4 to L4.

(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 K974757

Prescription Use X
(per 21 CFR 801.109)

OR Over-The-Counter Use _____