K970950
1 of 2

ISOLA SYSTEM
Easy Rod
510(k) SUMMARY

JUN - 3 1997

COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME:

Isola System Component- Easy Rod

CLASSIFICATION:

Spondylolisthesis Spinal Fixation Device
Unclassified, preamendment device system
Spinal Interlaminal Fixation Orthosis- Class II

DESCRIPTION:

The stainless steel Easy Rod is offered in 1/4 inch (6.35 mm) outer diameter and 18" (457 mm) in length. Generally, two rods are required in the construct and are cut to the appropriate length during the surgical procedure. The Easy Rod is a variation of rods previously cleared for the ISOLA Spinal System under K884163 and K944737.

MATERIAL:

The AcroMed Easy Rod is manufactured from implant grade (Grade 2 annealed) stainless steel conforming to ASTM F138 specifications, with a yield strength of 70-90 KSI.

INDICATIONS:

The ISOLA System consists of two sub-systems: The Posterior ISOLA system and the Anterior ISOLA System.

The ISOLA implants, when used with pedicle screws, are intended for use in Grade 3 or 4 spondylolisthesis at L5-S1 utilizing autologous bone graft, having the device fixed or attached to the lumbar and sacral spine, and intended to be removed after solid fusion is attained.

When not used with pedicle screws, the ISOLA System is intended for hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed surgery.

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INDICATIONS (Continued) :

As a whole, the Posterior ISOLA spinal system is intended for T1-sacral fixation. Pedicle screw fixation is from L3-S1.

The Anterior ISOLA system is intended for use in correcting scoliotic, lordotic or kyphotic spinal deformities by establishing an axially and rotationally rigid fixation bridge parallel to the long axis of the spine. The Anterior system is indicated in situations where loss of correction is expected, where severe scoliosis exists or where pelvic obliquity is present. Spinal levels for anterior instrumentation are from T5-L4.

The Easy Rod is intended to be used with the Posterior ISOLA system at this time.

PERFORMANCE DATA:

Static and fatigue testing show the AcroMed Easy Rod to perform consistent with previously cleared components.

SUBSTANTIAL EQUIVALENCE:

The AcroMed Easy Rod is equivalent to AcroMed's ¼ inch diameter ISOLA rod as cleared under K944737 and to the Harrington System, manufactured by Zimmer beginning in the 1960's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

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

Re: K970950
AcroMed Easy Rod to be used with
the ISOLA Spine System
Regulatory Class: II
Product Codes: MNH, KWP and KWQ
Dated: March 12, 1997
Received: March 14, 1997

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

Sincerely yours,

for 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): K970950

Device Name: AcroMed Easy Rod

Indications for Use:

The Easy Rod is a variation of the ¼ inch diameter ISOLA rod of the ISOLA Spine System. This rod offers the surgeon easier contourability and easier in-situ bending compared with existing ¼ inch diameter ISOLA rods. The ISOLA System consists of two sub-systems: The Posterior ISOLA system and the Anterior ISOLA System. The Easy Rod is intended to be used with the Posterior ISOLA system at this time.

The ISOLA implants, when used with pedicle screws, are intended for use in Grade 3 or 4 spondylolisthesis at L5-S1 utilizing autologous bone graft, having the device fixed or attached to the lumbar and sacral spine and intended to be removed after solid fusion is attained.

When not used with pedicle screws, the ISOLA System is intended for hook, wire, and/or sacral/iliac screw fixation from the T1 to the ilium/sacrum. The non pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed surgery.

As a whole, the Posterior ISOLA spinal system is intended for T1-sacral fixation. Pedicle screw fixation is from L3-S1.

The Anterior ISOLA system is intended for use in correcting scoliotic, lordotic or kyphotic spinal deformities by establishing an axially and rotationally rigid fixation bridge parallel to the long axis of the spine. The Anterior system is indicated in situations where loss of correction is expected, where severe scoliosis exists or where pelvic obliquity is present. Spinal levels for anterior instrumentation are from T5-L4.

Properly used, the Posterior and Anterior ISOLA Systems will provide temporary stabilization as an adjunct to spinal bone grafting processes. Specific indications are:

1. Idiopathic scoliosis.
2. Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spacisticity.
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. Neoplastic disease.
7. Revision surgery.

The Anterior ISOLA system is also 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 the hands.
5. Increasing pelvic obliquity coincident with back pain or loss of sitting balance.

(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 K970950

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

(Optional Format 1-2-96)