K981113

MAY 29 1998

# PEDIATRIC PRC
# for use with the ISOLA Spine System
## 510(k) SUMMARY

**COMPANY:**

**AcroMed Corporation**
3303 Carnegie Avenue
Cleveland, OH 44115

**TRADENAME:**

Pediatric PRC
for use with the ISOLA Spine System

**CLASSIFICATION:**

Labeled for pedicle screw use:
Unclassified, preamendments device system

Labeled for previously cleared uses:
Spinal interlaminal fixation orthosis;
Class II

**DESCRIPTION:**

The purpose of the premarket notification is to add a pediatric PRC (Plate-Rod Combination) and downsized hooks to the components intended for use with AcroMed's ISOLA Spine System.

**MATERIAL:**

All implant components are manufactured of either ASTM F-138 or F-1314 stainless steel or ASTM F-136 titanium alloy.

**INDICATIONS:**

The ISOLA Spinal System, when used with pedicle screws, is intended for use in grade 3 or 4 spondylolisthesis at L5-S1 utilizing autologous bone graft, when affixed to the lumbosacral spine, and intended to be removed after solid fusion is attained.

The ISOLA Spinal System, when not used with pedicle screws, 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 fusion.

As a whole, the ISOLA Spinal System is intended for T1-sacral fixation. Screw fixation is from L3-S1.

Benefit of spinal fusions utilizing any pedicle screw fixation 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.

**PERFORMANCE DATA:**

Static and fatigue testing were conducted to characterize the performance of the devices.

**SUBSTANTIAL EQUIVALENCE:**

The Pediatric PRCs, manufactured from stainless steel or titanium alloy, and the downsized hooks manufactured from titanium alloy are substantially equivalent to the ISOLA PRCs (K920392), titanium alloy ISOLA components (K952236), and to the Pediatric ISOLA components (K962984).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

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

Re: K981113
Pediatric PRC to be used with ISOLA Spinal System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: March 25, 1998
Received: March 27, 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). 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.

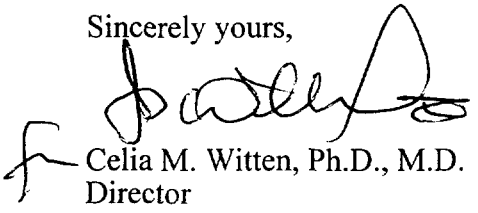
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 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 at (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): K981113**

**Device Name: ISOLA Spine System Pediatric PRC**

**Indications for Use:**

The ISOLA Spinal System, when used with pedicle screws, is intended for use in grade 3 or 4 spondylolisthesis at L5-S1 utilizing autologous bone graft, when affixed to the lumbosacral spine, and intended to be removed after solid fusion is attained.

The ISOLA Spinal System, when not used with pedicle screws, 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 fusion.

As a whole, the ISOLA Spinal System is intended for T1-sacral fixation. Screw fixation is from L3-S1.

(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 K981113

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

(Optional Format 1-2-96)

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