K962984
1 of 2

ISOLA SYSTEM

NOV 27 1996

ISOLA Pediatric Components

510(k) SUMMARY

COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME:

ISOLA Pediatric Components
used with the ISOLA System

CLASSIFICATION:

Spinal interlaminal fixation orthosis
Class II

DESCRIPTION:

The Pediatric ISOLA Components consist of side-tightening hooks with downsized dimensions to accommodate the anatomic limitations found where internal fixation is performed on pediatric or small stature individuals. The hooks are used with components already available in the ISOLA Spine System including 3/16 inch diameter rods, transverse connectors, sublaminar wires and cables, dual and tandem connectors, slotted connectors, sacral and iliac screws.

MATERIAL:

All implant components are manufactured of ASTM F-138 stainless steel.

INDICATIONS:

When labeled for pedicle screw fixation, the ISOLA implants are intended for use in grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral vertebral (L5-S1) joint utilizing autologous bone graft and intended to be removed after solid fusion is attained.

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.

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 surgery.

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

Contraindications for the use of the ISOLA System include active systemic infection or infection localized to the site of the proposed implantation. Severe osteoporosis may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia are relative contraindications. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, may place undue stresses on the implant.

PERFORMANCE DATA:

Static and fatigue testing show the constructs of the ISOLA Pediatric Components to perform consistently with previously cleared components.

SUBSTANTIAL EQUIVALENCE:

The ISOLA Pediatric components are equivalent to other ISOLA Components in intended use and attachment.