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**ISOLA SYSTEM**  
**AcroMed Pedicle Screw (4.75 mm)**  
**510(k) SUMMARY**

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

**TRADENAME:** AcroMed Pedicle Screw

**CLASSIFICATION:** Spondylolisthesis Spinal Fixation Device  
Unclassified, preamendment device system

**DESCRIPTION:** The AcroMed Pedicle Screw is composed of two sections: a long cancellous section with an integral fixed lower nut, and a machine threaded section topped with an hexagonal drive head. The integral nut serves two purposes: it creates a stronger bolt connection between the screw and rod and it eliminates the "claw hammer" effect associated with other screw designs.

The AcroMed Pedicle Screw is supplied with an adjustable tapered nut and an optional lock nut, which enables a pedicle screw and a slotted connector to be adjoined utilizing a locking nut system. The junction point of the adjustable integral nut and machine thread portion of the pedicle screw is also rounded to reduce potential stress concentration.

The screw is available in cancellous thread lengths from 25-50 mm, in 5 mm increments.

**MATERIAL:** The AcroMed Pedicle Screw is manufactured from implant grade stainless steel conforming to ASTM F1314 specifications.

**INDICATIONS:**

The AcroMed Pedicle Screw is designed to be utilized with the ISOLA Spine System (K944737). 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 and intended to be removed after solid fusion is attained.

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

The component that is the subject of this premarket notification, the 4.75 mm diameter pedicle screw, is a line extension version of AcroMed Pedicle Screws previously cleared under K951657 for the ISOLA system. It is intended for use in pediatric and other applications where anatomic considerations limit the size of the implants that can be used for internal fixation applications.

**PERFORMANCE DATA:**

Static and fatigue testing show the AcroMed pedicle screws (4.75 mm) to perform consistently with previously cleared components.

**SUBSTANTIAL EQUIVALENCE:**

The AcroMed 4.75 mm diameter pedicle screw is equivalent to other AcroMed pedicle screws as cleared under K951116.