OCT 21 1998

ISOLA SPINAL SYSTEM
Pedicle Screw Indications
510(k) SUMMARY

COMPANY:

DePuy AcroMed, Inc.
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME:

ISOLA Spinal System

CLASSIFICATION:

Labeled for pedicle screw use: Class II

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

DESCRIPTION:

The primary purpose of this premarket notification is to add indications to the marketing clearance for the pedicle screws which may be used as a spinal anchor in the 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 Posterior ISOLA Spinal System, when used with pedicle screws, is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The Posterior ISOLA Spinal System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

The Posterior 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 surgery.

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 system is indicated in situations where loss of correction is expected, where severe scoliosis exists or where pelvic obliquity is present.

The Anterior ISOLA system is 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. Specific indications 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.
6. Spinal fractures (acute reduction or late deformity)
7. Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).
8. Spinal tumor
9. Previous failed fusion surgery.

Spinal levels for Anterior ISOLA instrumentation are from T5-L4.

PERFORMANCE DATA:

Static and fatigue testing shows the constructs of the ISOLA Spinal System to perform consistently with previously cleared components.

SUBSTANTIAL EQUIVALENCE:

The ISOLA Spinal System manufactured from stainless steel or titanium alloy is substantially equivalent, for purposes of this 510(k) adding indications, to the Townley Screw previously marketed by Zimmer and the CD Spinal System currently marketed by Sofamor Danek.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

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

Re: K980485
Trade Name: ISOLA Spinal System
Regulatory Class: II
Product Codes: MNI, KWQ, KWP, and MNH
Dated: August 20, 1998
Received: August 24, 1998

Dear Mr. Christianson:

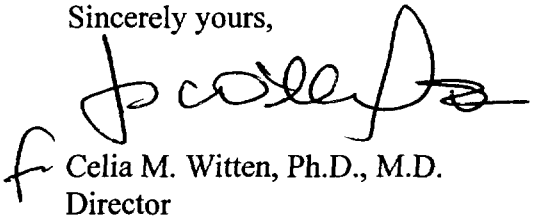
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, 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 the device, subject to the general controls provisions of the Act. 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.

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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, 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): K980485

Device Name: ISOLA Spine System (Titanium and Stainless Steel)

Indications for Use:

The Posterior ISOLA Spinal System, when used with pedicle screws, is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The Posterior ISOLA Spinal System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980485

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

(Optional Format 1-2-96)

510(k) Number (if known): K980485

Device Name: ISOLA Spine System (Titanium and Stainless Steel)

Indications for Use:

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 system is indicated in situations where loss of correction is expected, where severe scoliosis exists or where pelvic obliquity is present.

The Anterior ISOLA system is 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. Specific indications include:

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7. Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).
8. Spinal tumor
9. Previous failed fusion surgery.

Spinal levels for Anterior ISOLA instrumentation are from T5-L4.

Prescription Use X
(per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980485