K013403

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Section 7 - 510(k) Summary of Safety and Effectiveness

7.1 Statement

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2 Submitter

Endius, Inc.
23 West Bacon Street
Plainville, MA. 02762

7.3 Company Contact

Susan Finneran
Director RA
508-643-0983 Ext. 114

7.4 Device Name

Proprietary Name:
Tri-Fix Spinal Fixation System
Common Name:
Pedicle Screw System , Non-pedicle spinal fixation system
Classification Name:
Spinal Pedicle Screw (MNI),Spinal Interlaminal fixation orthosis (KWP), Spondylolithesis Spinal Fixation Device System (MNH)

7.5 Predicate Legally Marketed Devices

The Washerless Plate with the new nut design is substantially equivalent to the Washerless Plate that was originally cleared via K010903.

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7.6 Device Description

The TrFix Washerless Plate system is intended to be used for posterior lumbar fusion procedures. The system is manufactured from titanium which complies with ASTM F136. The components, which are included as part of the system, include screws, rods, plates, and accessory connection components.

7.7 Device Indications and Intended Use

The TriFix Spinal System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar, and sacral spine.

The Tri-Fix Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The posterior Tri-Fix Spinal System is also indicated for pedicle screw fixation for severe spondylolithesis (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 Tri-Fix System, when not used with pedicle screws is indicated for hook, wire, and /or sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolithesis, 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.

7.8 Substantial Equivalence

The Washerless Plate with the new nut design is substantially equivalent to the Washerless Plate that was originally cleared via K010903.

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7.10 Summary of Non-Clinical Tests

Biomechanical testing according to ASTM F1717 was completed on Washerless Plate constructs with the new nut to demonstrate equivalence to previously cleared components of the TriFix system. Corpectomy constructs were fabricated using Washerless plates (previously cleared) with the new nut (the subject of this 510k) and tested according to ASTM F1717.

Both static and fatigue compression tests were completed and the results demonstrated that the new component (nut) is substantially equivalent to previously cleared components of the TriFix system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2001

Ms. Susan Finneran
Director Regulatory Affairs/ Clinical Sciences
Endius, Inc.
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K013403
Trade Name: Tri-Fix Washerless Plate System
Regulatory Class: Class III
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Product Code: MNI, MNH, KWP
Dated: October 12, 2001
Received: October 13, 2001

Dear Ms. Finneran:

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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 4 2001

K013403

510(k) Number (if known): K013403

Device Name: Tri-Fix Washerless Plate System (Stainless Steel and Titanium)

Indications for Use:

The TriFix Spinal System is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar, and sacral spine.

The Tri-Fix Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013403