MAR 1 1 2002

K014090

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

Gene DiPoto
Vice President of Engineering
508-643-0983 Ext. 104

7.4 Device Name

Proprietary Name:
Endius 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 Endius Spinal Fixation System is substantially equivalent to the TriFix Spinal System manufactured by Endius, Inc.

7.6 Device Description	The Endius Spinal Fixation System is a system that 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 Endius Spinal Fixation 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 the thoracic, lumbar, and sacral spine. The Endius Spinal Fixation 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The Endius Spinal Fixation 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 obtained. Levels of fixation are L3-S1. In addition, the Endius Spinal Fixation System, when not used with pedicle screws, is indicated for posterior hook and sacral screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis, and kyphosis), tumor, fracture, and previously failed fusion surgery.
7.8 Substantial Equivalence	The Endius Spinal Fixation System is substantially equivalent to the TriFix Spinal System manufactured by Endius, Inc.

7.9 Table of Substantial Equivalence

Device Name	Endius Spinal Fixation System	TriFix Spinal System
Indications for Use	See above	Identical
Materials	Titanium	Stainless Steel or Titanium
Product Labeling	Instructions for use and box labeling including all of the necessary warning statements	Instructions for use and box labeling including all of the necessary warning statements
Packaging/ Sterilization	Non-sterile, single use only	Non-sterile, single use only
Biomechanical Test Results	Complies with ASTM F1717	Complies with ASTM F1717

Applicant_____ Date_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2002

Mr. Gene DiPoto
Vice President of Engineering
Endius Incorporated
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K014090
Endius Spinal Fixation System
Regulation Numbers: 888.3050 and 888.3070
Regulation Names: Spinal Interlaminal Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System; and Pedicle Screw Spinal System
Regulatory Classes: III
Product Codes: KWP, MNH and MNI
Dated: December 10, 2001
Received: December 11, 2001

Dear Mr. DiPoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

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

510(k) Number (if known): K014090

Device Name: Endius Spinal Fixation System (Titanium)

Indications for Use:

The Endius Spinal Fixation 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 the thoracic, lumbar, and sacral spine.

The Endius Spinal Fixation 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Endius Spinal Fixation 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 obtained. Levels of fixation are L3-S1.

In addition, the Endius Spinal Fixation System, when not used with pedicle screws, is indicated for posterior hook and sacral screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis, and kyphosis), tumor, fracture, and previously failed fusion surgery.

for Mark N Milhous

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

510(k) Number K014090

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)