P1/2 K010922

JUN - 6 2001

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 new transverse connector components of the TriFix Spinal System are substantially equivalent to the previously cleared Tri-Fix Spinal System cleared via K992147.

P2/2 K010922

7.9 Table of Substantial Equivalence

Device Name	Tri-Fix Spinal System Transverse Connectors (Cleared)	Tri-Fix Spinal System Transverse Connectors (New designs)
Indications for Use	See above	Identical
Materials	Stainless Steel or 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	Cleared	Comparable values obtained

Applicant _____ Date 3/26/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

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

Re: K010922
Trade Name: Tri-Fix Spinal Fixation System
Regulatory Class: Class II
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050,
Product Code: MNI, MNH, KWP,
Dated: March 26, 2001
Received: March 27, 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,

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): K010922

Device Name: Tri-Fix Spinal Fixation System (Stainless Steel and Titanium)

Indications for Use:
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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

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

510(k) Number K010922