OCT - 2 2000

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

K002437

7.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92

7.2 Submitter	Endius, Inc. 23 West Bacon Street Plainville, MA. 02762 (USA)

7.3 Company Contact	Susan Finneran QA/RA Manager, Endius, Inc.) 508-643-0983

7.4 Device Name/ Classification	Proprietary Name: Endius Endoscopic Access System Common Name: Endoscopic Spinal Access System Classification Name: Endoscope and Accessories The devices in the Endoscopic Spinal Access System can be classified as class II, 876.1500 Endoscope and Accessories. The primary device in the system is the endoscope. The accessory equipment is needed to gain access for placement of the endoscope, to support the endoscope in position, or to work with the endoscope for the purpose of visualization.

7.5 Predicate Legally Marketed Devices	Sofamor Danek Microendoscopic Discectomy System (Sofamor Danek Memphis, Tennessee)

7.6 Device Description

The Endoscopic Access System includes instruments used to access the spine by dilation of the overlying tissues, as well as a retracting device that is used to maintain the access. Once the retractor is in place, the visualization components of the system may be used. These include, an endoscope, a light source, light guide, a camera control unit, and a camera head.

The Endoscope may be used to visualize the operative site. When using the system for discectomy, nucleotomy, or non-instrumented posterolateral fusion procedures the retractor used with the system has a 16mm diameter tube portion and expands distally in the range of 25-35mm.

When the system is used for the placement of pedicle screws a larger retractor may be used. The larger sized retractor has a 20mm diameter tube portion and expands distally in the range of 30-40mm.

The camera head, scope, and light guide are supported by a circular mount, which allows manual 360-degree rotation of the scope. The mount is connected to a vacuum powered arm that may be used to manipulate the construct in any position.

7.7 Indications for Use

The Endius Endoscopic Access System is indicated for use in instrumented posterolateral fusion procedures where the TriFix Spinal Instrumentation System is utilized.
The Endius Endoscopic Access System is also intended to be used for posterior endoscopic access to the lumbar spine for various endoscopic spinal procedures such as discectomy, nucleotomy, non-instrumented posterolateral fusion procedures.

7.8 Substantial Equivalence

The Endius Endoscopic Spinal Access System is substantially equivalent to the Sofamore Danek USA Microendoscopic System (Memphis, TN)
A summary of the features of the two systems follows:

Table of Substantial Equivalent Device Similarities		
	MED System	**Endius Spinal Access**
Product Components	• Guidewire/ Dilator Set • Tubular Retractor • Endoscope • Light Source • Camera and Control unit • Flexible Arm Assembly	• Guidewire and Dilator Set • Flexposure Retractor • Endoscope • Light Source • Camera and control unit • Flexarm and Scope retractor Mount
Product Labeling	Non-sterile, Reusable For all components with the exception of the scope	Non-sterile, Reusable for all components except Flexposure retractor
Materials	Material composition is primarily Stainless Steel and Anodized Aluminum	Material composition is primarily Stainless Steel and Anodized Aluminum
Indications	Posterior lateral visualization	Access to the spine for various spinal repair procedures including nucleotomy, discectomy, non-instrumented fusion procedures, and instrumented fusion procedures when the TriFix Pedicle screw system is used.
Intended use	The System is used to access the lumbar Spine	The system will be used to access the lumbar spine.

Applicant _____ Date 8/9/00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2000

Ms. Susan Finneran
Quality Assurance, Regulatory Affairs Manager
Endius, Inc.
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K002437
Trade Name: Endius Endoscopic Access System
Regulatory Class: II
Product Code: HRX
Dated: August 8, 2000
Received: August 9, 2000

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) 594-4595. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Mark N Melkerson

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

510(k) Number (if known): K002437

Device Name: Endius Endoscopic Access System

Indications for Use: The Endius Endoscopic Access System is indicated for use in instrumented posterolateral fusion procedures where the TriFix Spinal Instrumentation System is utilized. The Endius Endoscopic Access System is also intended to be used for posterior endoscopic access to the lumbar spine for various endoscopic spinal procedures such as discectomy, nucleotomy, non-instrumented posterolateral fusion procedures.

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Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Mark N. Milhorn

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002437