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K994425
2 pages

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
QA/ RA Manager
508-643-0983

7.4 Device Name: Proprietary Name: Endoscopic Spinal Access System
Common Name: Endoscopic Spinal Access System
Classification Name: Endoscope and Accessories

7.5 Predicate Legally Marketed Devices MicroEndoscopic Discectomy System
Sofamor Danek USA
Memphis, TN. 38132

7.6 Device Description The Endoscopic Spinal Access System is a family of devices which are intended to be used to gain access and visualization to the spine in order to aid in various spinal procedures.

7.7 Device Indications and Intended use Indications for Use: the Endius Endoscopic Access System is intended to be used for posterior endoscopic access to the lumbar spine for various endoscopic spinal procedures such as discectomy, nucleotomy and non-instrumented posterolateral fusion procedures.

Warning: The Endius Endoscopic Access System is not intended to be

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used for other types of fusion procedures such as posterior lumbar interbody fusions (non-instrumented or instrumented) or posterolateral fusions which employ instrumentation.

**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	<ul style="list-style-type: none"> • Guidewire/ Dilator Set • Tubular Retractor • Endoscope • Light Source • Camera and Control unit • Flexible Arm Assembly 	<ul style="list-style-type: none"> • 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	Various Spinal procedures such as discectomy, nucleotomy, non-instrumented posterolateral fusions.
Intended use	The System is used to access the lumbar Spine	The system will be used to access the lumbar spine.

Applicant

Susan J...

Date

12/28/99



FEB 16 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994425
Trade Name: Endius Endoscopic Access System
Regulatory Class: II
Product Code: HRX
Dated: December 29, 1999
Received: December 30, 1999

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.

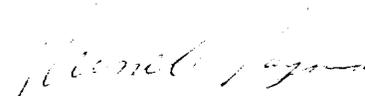
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Ms. Susan Finneran

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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 994425

Device Name: Endius Endoscopic Access System

Indications for Use: the Endius Endoscopic Access System is intended to be used for posterior endoscopic access to the lumbar spine for various endoscopic spinal procedures such as discectomy, nucleotomy and non-instrumented posterolateral fusion procedures.

Warning: The Endius Endoscopic Access System is not intended to be used for other types of fusion procedures such as posterior lumbar interbody fusions (non-instrumented or instrumented) or posterolateral fusions which employ instrumentation (pedicle screws/cages)

Muskel
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 994425

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use X
(Per 21 CFR 801.109)