2/24/99

K983144

510(k) Summary
for
Endius Incorporated
Flexposure Retractor

1. SPONSOR

Endius Incorporated
23 West Bacon Street
Plainville, MA 02762
Telephone: 508-643-0983
Facsimile: 508-695-2501

Contact Person: Mark Bliss

Date Prepared: September 4, 1998

2. DEVICE NAME

Proprietary Name:	Flexposure Retractor
Common/Usual Name:	Retractor
Classification Name:	Manual Surgical Instrument

3. PREDICATE DEVICES

Retractor included in the Sofamor Danek MED Microendoscopic Discectomy, K955471, K950501 and K950130.

4. DEVICE DESCRIPTION

The Flexposure Retractor is a manual surgical instrument intended for use in posterior endoscopic microdiscectomy procedures. It is essentially a standard retractor designed to improve exposure of the surgical site. The Flexposure Retractor looks like a standard retractor/tube like device with the exception of the distal end. The distal end of the device can expand to better retract tissues from the operative site. The device includes a tip release line which is attached to an outer heat shrink polyester material. The purpose of the heat shrink polyester

material is to maintain the retractor in the closed position. The remainder of the device is made from medical grade stainless steel.

The Flexposure Retractor is placed several centimeters lateral to the midline of the back through a cannula. The tip of the Retractor is positioned on the lamina. After positioning, the user pulls the tip release line which causes the heat shrink polyester material to split. The splitting of the heat shrink material allows for the expansion of the tip of the cannula. A mechanical hand held retractor is inserted through the cannula and opened causing the flexible stainless steel skirt of the retractor to be expanded to approximately a 25 mm dimension.

5. INTENDED USE

The Flexposure Retractor is a disposable manual surgical instrument intended to provide endoscopic access to the posterior lumbar spine by retracting tissues during endoscopic discectomy procedures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Endius Incorporated Flexposure Retractor is substantially equivalent to several legally marketed retractors including the retractor included in the Sofamor Danek MED Microendoscopic Discectomy, K955471, K950501 and K950130.

Both the Endius Retractor and the predicate Sofamor Danek retractor are intended to provide endoscopic access to the posterior lumbar spine by retracting tissues during endoscopic discectomy procedures.

Both the Endius Retractor and the predicate Sofamor Danek retractor are similar in that they are inserted over step dilators to push the tissues away from the operative site. The Endius Retractor is different in that the distal tip of the retractor expands to provide improved endoscopic access to the posterior lumbar spine. This difference does not compromise safety or effectiveness of the device since the device functions essentially identical to the predicate device in retracting tissues. The only difference is the method of retraction. The materials of manufacture of both the proposed and predicate devices are medical grade stainless steel.

Based on the above discussion and the comparison chart below, Endius Incorporated believes that the Flexposure Retractor is substantially equivalent to the Sofamor Danek Retractor of the MED System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Endius, Inc.
c/o Ms. Mary McNamara-Cullinane
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K983144
Trade Name: Flexposure Retractor
Regulatory Class: II
Product Code: HRX
Dated: December 7, 1998
Received: December 8, 1998

Dear Ms. McNamara-Cullinane:

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,

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

Enclosure

510(k) Number (if known): K983144

Device Name: Flexposure Retractor

Indications For Use:

The Flexposure Retractor is a manual surgical instrument intended to provide endoscopic access to the posterior lumbar spine by retracting tissues during endoscopic discectomy procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983144

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)