AUG 2 3 2002

K022578
1 of 2

Section 7 - 510(k) Summary

7.1 Statement

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Endius, Inc. is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Endius, Inc. chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the modified device, Endius® FlexTip® Blade is provided below.

7.2 Submitter

Endius, Inc.
23 West Bacon Street
Plainville, MA. 02762

7.3 Company Contact

Christine Kuntz-Nassif
Director, Regulatory Affairs
508-643-0983 Ext. 114

7.4 Device Name

Proprietary Name:
Endius® FlexTip® Blade
Common Name:
Arthroscopic Accessory: Bendable Shaver
Classification Name:
Arthroscope (HRX)

7.5 Predicate Device

Endius Endo-Bend Shaver System: K950054

7.6 Device Description	The Endius FlexTip Blade is a disposable, articulating soft tissue resector designed to be used as an accessory to the Arthroscopic Micro-Discectomy (AMD) System or compatible drive systems. The FlexTip Blade has a flexible portion near the tip, allowing the tip to articulate under control of the lever in the handle. The inner shaft rotates inside the outer shaft providing cutting action through an aperture at the tip. Resected material is suctioned through the inner shaft and shaver handle into an inline external tissue trap. The Endius FlexTip Blade is sold sterile for single-use only.
7.7 Device Indications For Use	The Endius® FlexTip® Bladeis an articulating soft tissue resector designed to be used as an accessory to an Arthroscopic Micro-discectomy (AMD) system or an equivalent and compatible drive system, to perform percutaneous lumbar discectomies.
7.8 Substantial Equivalence	The proposed Endius FlexTip BladeSystem is substantially equivalent to the Endius Endo-Bend System, K950054.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2002

Endius, Inc.
Christine Kuntz-Nassif
Director, Regulatory Affairs
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K022578
Trade/Device Name: Endius® Flextip® Blade
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 2, 2002
Received: August 5, 2002

Dear Ms. Kuntz-Nassif:

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.

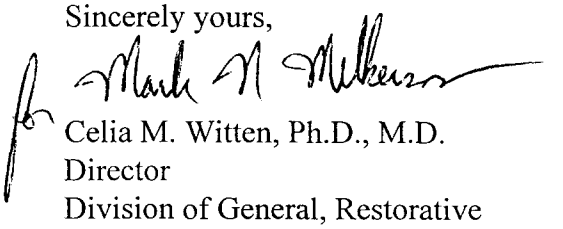
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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,



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):

Device Name: Endius® FlexTip® Blade

Indications for Use:

The Endius® FlexTip® Blade is an articulating soft tissue resector designed to be used as an accessory to an Arthroscopic Micro-discectomy (AMD) system or an equivalent and compatible drive system, to perform percutaneous lumbar discectomies.

(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)

Mark N Milhous

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

510(k) Number K022578