JUN 2 6 2002

K021748

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 Atavi System is provided below.
7.2 Submitter	Endius, Inc. 23 West Bacon Street Plainville, MA. 02762 (USA)
7.3 Company Contact	Christine Kuntz-Nassif Director, Regulatory Affairs Endius, Inc. 508-643-0983
7.4 Device Name/ Classification	Proprietary Name: Endius Atavi System Common Name: Endoscopic Spinal Access System Classification Name: Endoscope and Accessories The devices in the Endoscopic Atavi 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	Endius Endoscopic Access System: K991794, K994425, K002437
7.6 Device Description	The Endius Atavi 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. The visualization components of the system include, an endoscope, a light source, light guide, a camera control unit, and a camera head.
7.7 Indications for Use	The Endius Atavi System is indicated for use in instrumented posterolateral fusion procedures where the TriFix Spinal Instrumentation System is utilized. The Endius Atavi 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.
7.7 Safety and Performance	This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Endius, Inc. has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and the results of validation testing (performance testing) for the device modification.

7.8 Substantial Equivalence

Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed Endius Atavi System has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

Applicant _____ Date 5/24/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN 2 6 2002

Re: K021748
Trade/Device Name: Endius® Atavi™ System
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: May 24, 2002
Received: May 28, 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" (21CFR 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,

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): K021748

Device Name: Endius® Atavi™ System

Indications for Use:

The Endius Atavi System is indicated for use in instrumented posterolateral fusion procedures where the TriFix Spinal Instrumentation System is utilized.

The Endius Atavi 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.

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

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

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

510(k) Number K021748