JUN - 6 2006

K061345

May 12, 2006

Section 5 - 510(k) Summary

5.1 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.

5.2 Submitter

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

5.3 Company Contact

Christine Kuntz-Nassif
Director, Regulatory Affairs/Quality Assurance
Phone: (508) 643-0983 x114
Fax: (508) 695-2501
Email: cnassif@endius.com

5.4 Device Name

Proprietary Name: Endius Atavi 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.

5.5 Predicate Devices

Device Name(s): Endius Atavi System
510(k) Number(s): K991794, K994425, K002437, K021748, K022199, K053267

5.6 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.

5.7 Device Indications and Intended Use

The Endius® Atavi™ System is indicated for use for posterior or anterior access and visualization in the surgical area of the cervical, thoracic, or lumbar spine allowing the surgeon to perform any type of surgical spinal procedures such as discectomy, nucleotomy, spinal fusion, spinal decompression, and insertion of spinal implants. Other examples of generic surgical use of the Endius® Atavi™ System would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

5.8 Substantial Equivalence

The proposed Endius Atavi System is substantially equivalent to the current Endius Atavi System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Endius, Inc.
% Ms. Christine Kuntz-Nassif
Director, Regulatory Affairs/Quality
Assurance
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K061345
Trade/Device Name: Endius® Atavi System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulation Class: II
Product Code: HRX
Dated: May 12, 2006
Received: May 16, 2006

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K06xxxx** K061345

Device Name: **Endius® Atavi System**

Indications For Use:

The Endius Atavi System is indicated for use for posterior or anterior access and visualization in the surgical area of cervical, thoracic, or lumbar spine allowing the surgeon to perform any type of surgical spinal procedures such as discectomy, nucleotomy, spinal fusion, spinal decompression, and insertion of spinal implants. Other examples of generic surgical use of the Endius Atavi system would be for use in the knee, ankle, shoulder, hand, wrist, and temporomandibular joint (TMJ).

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061345