K060683

Section 5 - 510(k) Summary

APR 19 2006

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® Minit Posterior Cervical and Upper Thoracic Fixation System is provided below.

5.2 Submitter

Endius, Inc.
23 West Bacon Street
Plainville, MA. 02762
Establishment Registration #: 1057469

5.3 Company Contact

Christine Kuntz-Nassif
Director, Regulatory Affairs/Quality Assurance
(508) 643-0983 x114
cnassif@endius.com

5.4 Device Name

Proprietary Name: Endius Minit Posterior Cervical and Upper Thoracic Fixation System
Classification Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: KWP
Regulation Number: 21 CFR 888.3050

5.5 Predicate Devices

Device Name(s) & 510(k) Number:

- Medtronic Sofamor Danek VERTEX Reconstruction System, K052180
- Synthes Spine Cervifix (K991089, K001864) and Starlock Systems

5.6 Device Description

The Endius Minit Posterior Cervical and Upper Thoracic Fixation System is a posterior system, which consists of a variety of sizes of rods, hooks, screws, multi-axial screws and connecting components, which can be rigidly locked to the rod in a variety of configurations. The Minit System is fabricated from medical grade titanium or titanium alloy that complies with ASTM F136.

5.7 Device Indications and Intended Use

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the Endius Minit Posterior Cervical and Upper Thoracic Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

Hooks and Rods
The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Screws/Connectors
The use of screws is limited to placement in the T1-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

5.8 Substantial Equivalence

Documentation, including mechanical test results, has been provided which demonstrates that the proposed Endius Minit Posterior Cervical and Upper Thoracic Fixation System components are substantially equivalent to the Medtronic VERTEX Reconstruction System (K052180) and Synthes Spine Cervifix (K991089, K001864) and Starlock Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2006

Endius, Inc.
c/o Ms. Christine Kuntz-Nassif
Director, RA/QA and Tissue Banking
23 West Bacon Sr.
Plainville, Massachusetts 02762

Re: K060683
Trade/Device Name: Endius Minit Posterior Cervical and Upper Thoracic Fixation
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: March 14, 2006
Received: March 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) 276-0120. 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/industry/support/index.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**

Device Name: **Endius® Minit Posterior Cervical and Upper Thoracic Fixation System**

Indications For Use:

When intended to promote fusion of the cervical spine and the thoracic spine, (C1-T3), the Endius Minit Posterior Cervical and Upper Thoracic Fixation System is indicated for the following:

DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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 K060683

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