SEP - 6 2007

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 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

Regina Wagner
Manager, Regulatory Affairs/Quality Assurance

(508) 643-0983 x107
rwagner@endius.com

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: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3050

5.5 Predicate Devices

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

- Endius Minit Posterior Cervical and Upper Thoracic Fixation System, K060683

5.6 Device Description

The proposed 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.

Axial and Offset Rod Connectors

The Minit Posterior Cervical and Upper Thoracic Fixation System can also be linked to the TiTLE and TiTLE2 Polyaxial Spinal Systems offered by Endius Inc. using the Axial Rod Connectors, Dual Rod Connectors and the Tri Screw Dual Rod Connectors.

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 legally marketed similarly indicated predicate devices which have been tested in a similar manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP - 6 2007

Re: K070282
Trade/Device Name: Endius Minit Posterior Cervical-Thoracic Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: August 21, 2007
Received: August 22, 2007

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.

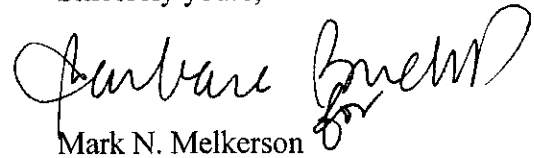
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Indications for Use

510(k) Number (if known): K070282

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.

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.

Axial and Offset Rod Connectors

The Minit Posterior Cervical and Upper Thoracic Fixation System can also be linked to theTiTLE and TiTLE 2 System offered by Endius Inc. using the Axial Rod Connectors, Dual Rod Connectors and the Tri Screw Dual Rod Connectors.

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) for MAY

Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K070282