K121276

5. 510(K) SUMMARY

AUG 29 2012

Submitter's Name:	NeuroVention LLC
Submitter's Address:	311 N. Clyde Morris Blvd Suite 580 Daytona Beach, FL 32114
Submitter's Telephone:	(386) 257-5055
Contact Name:	Rohit Khanna
Date Summary was Prepared:	30 March 2012
Trade or Proprietary Name:	NeuroVention LamiFix Laminoplasty Plating System
Common or Usual Name:	Orthosis, Spine, Plate, Laminoplasty, Metal
Classification:	Class II per 21 CFR §888.3050
Product Codes:	NQW
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Device:	Synthes Arch™ Fixation System (AFS) (K032534)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The NeuroVention LamiFix Laminoplasty Plating System is comprised of various sized, pre-bent mini-plates that are designed to fit the anatomy of the vertebral arch (i.e., between the pedicle and spinous process). The plates have screw holes located at the center and both ends of the plate to allow for attachment to the bone. The center hole in the plate is used for attachment to bone allograft spacers that are provided in a variety of sizes. The screws intended for use with the mini-plates are available in a variety of lengths and diameter and are designed to match the anatomical requirements.

INDICATIONS FOR USE

The NeuroVention LamiFix Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The NeuroVention LamiFix Laminoplasty Plating System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

The indications for use for the NeuroVention LamiFix Laminoplasty Plating System are similar to that of the Synthes Arch™ Fixation System (AFS).

TECHNICAL CHARACTERISTICS

The NeuroVention LamiFix Laminoplasty Plating System plates and screws are manufactured from titanium alloy (ASTM F136), and the spacers are manufactured from allograft, similar to the referenced predicate devices. No new technical characteristics are being introduced with this product.

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PERFORMANCE DATA

The NeuroVention LamiFix Laminoplasty Plating System was tested in static axial compression bending, static torsion, and dynamic axial bending compression per modified ASTM F1717–11 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that NeuroVention LamiFix Laminoplasty Plating System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 29 2012

Neurovention, LLC
% Empirical Testing Coporation
Ms. Meredith May
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K121276
Trade/Device Name: NeuroVention LamiFix Laminoplasty Plating System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: March 30, 2012
Received: August 03, 2012

Dear Ms. May:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

K121276

Device Name: NeuroVention LamiFix Laminoplasty Plating System

The NeuroVention LamiFix Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The NeuroVention LamiFix Laminoplasty Plating System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121276