K091623

5. 510(K) SUMMARY

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Ms. Han Fan
Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Boulevard
San Diego, California 92121
Telephone: (858) 909-3338
Fax: (858) 909-3438

OCT - 9 2009

B. Device Name

Trade or Proprietary Name:	*NuVasive Laminoplasty Fixation System*
Common or Usual Name:	Interlaminal Fixation Appliance
Classification Name:	Spinal Interlaminal Fixation Orthosis
Device Class:	Class II
Classification:	§888.3050
Product Code:	NQW

C. Predicate Devices

The subject device is substantially equivalent to similar previously cleared device, Synthes's Arch™ System (K032534) that is currently distributed commercially in U.S.

D. Device Description

The *NuVasive Laminoplasty Fixation System* consists of different sizes of plates and screws that can be rigidly locked to suit the individual pathology and anatomical conditions of the patient.

E. Intended Use

The *NuVasive Laminoplasty Fixation System* is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Laminoplasty Fixation System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

F. Substantial Equivalence

Data was provided which demonstrated the *NuVasive Laminoplasty System* to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material, and function.

G. Summary of Non-Clinical Tests

Mechanical testing was presented.

H. Summary of Clinical Tests (Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Incorporated
% Ms. Han Fan
Regulatory Affairs Specialist
7475 Lusk Boulevard
San Diego, California 92121

OCT - 9 2009

Re: K091623
Trade/Device Name: NuVasive® Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: NQW
Dated: September 25, 2009
Received: September 28, 2009

Dear Ms. Fan:

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 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 (240) 276-3150 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

510(k) Number (if known): K091623

Device Name: *NuVasive® Laminoplasty Fixation System*

Indications for Use:

The *NuVasive Laminoplasty Fixation System* is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Laminoplasty Fixation System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091623