NUVASIVE

Affix® Spinous Process Plate System
June 27, 2013

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Sheila Bruschi
Regulatory Affairs Manager
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: June 27, 2013

B. Device Name

Trade or Proprietary Name:	*Affix® Spinous Process Plate System*
Common or Usual Name:	Spinal interlaminal fixation orthosis
Classification Name:	Spinal interlaminal fixation orthosis
Device Class:	Class II
Classification:	21 CFR § 888.3050
Product Code:	PEK

C. Predicate Devices

The subject *Affix Spinous Process Plate System* is substantially equivalent to the predicate device, NuVasive Spinous Process Plate System (K073278) and Osteomed PrimaLOK SP (K100354).

D. Device Description

The *Affix Spinous Process Plate* is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1–S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion, and is not intended for stand-alone use. When the Affix Plate is used as supplemental fixation in interbody fusion procedures, its use is limited to the treatment of degenerative disc disease (DDD) of the lumbosacral spine (L2-S1).

E. Intended Use

The *Affix Spinous Process Plate System* is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Tumor

The *Affix Spinous Process Plate System* is not intended for stand-alone use.

F. Technological Characteristics

As was established in this submission, the subject *Affix Spinous Process Plate System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

The purpose of this 510(k) is to modify the Surgical Technique for the subject *Affix Spinous Process Plate System*. No other changes have been made to the predicate Affix System cleared in K073278. Therefore, no new performance data was generated for the purpose of this submission.

H. Conclusions

The subject *Affix Spinous Process Plate System* has been shown to be substantially equivalent to legally marketed predicate devices in terms of safety and effectiveness, having similar indications for use, technological characteristics, and principles of operation as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 2, 2013

NuVasive, Incorporated
% Ms. Sheila Bruschi
Regulatory Affairs Manager
7475 Lusk Boulevard
San Diego, California 92121

Re: K131238
Trade/Device Name: Affix® Spinous Process Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: April 30, 2013
Received: May 1, 2013

Dear Ms. Bruschi:

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 contact 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. 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,

Erin D Keith

For

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

Enclosure

Indications for Use

510(k) Number (if known): K131238

Device Name: Affix® Spinous Process Plate System

Indications For Use:

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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)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131238