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

Ms. Sheila Bruschi
Senior Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Boulevard
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Telephone: (858) 320-4515
Fax: (858) 320-4615
Date 510(k) Summary Prepared: May 6, 2010

B. Device Name

Trade or Proprietary Name: *NuVasive® Facet Screw System*

Common or Usual Name:	Posterior Facet Screw and Washer
Classification Name:	Facet Screw Spinal Device System
Device Class:	Unclassified
Classification:	Unclassified
Product Code:	MRW

C. Predicate Devices

The subject *NuVasive Facet Screw System* is substantially equivalent to the following devices previously cleared by FDA: DePuy AcroMed DISCOVERY Facet Screw Fixation System (K012773), NuVasive® Triad® Facet Screw System (K020411), Spineology® Facet Screw System (K092464), and the TransS1® Facet Screw (K073515).

D. Device Description

The *NuVasive Facet Screw System* consists of fully threaded and partially threaded screws designed to compact juxtaposed facet articular processes to enhance spinal fusion and stability. The screws and washers are fabricated from anodized titanium alloy (Ti-6Al-4V) and are supplied in various sizes to accommodate the various anatomy of the spine.

E. Intended Use

The *NuVasive® Facet Screw System* is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The *NuVasive Facet Screw System* is indicated for facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1 (inclusive). The *Facet Screw System* is indicated for treatment of any or all of the following:

(a) pseudoarthrosis and failed previous fusion;
(b) spondylolisthesis;
(c) spondylolysis;
(d) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies;

(e) degeneration of the facets with instability; and
(f) fracture.

The NuVasive *Facet Screw System* is intended for conventional or percutaneous surgical placement.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Facet Screw 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 the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NuVasive Facet Screw System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic cantilever bending testing (with guidance by ASTM F1717-04)

The results of this study showed that the subject *NuVasive Facet Screw System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NuVasive Facet Screw System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

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

NuVasive, Inc.
% Ms. Sheila Bruschi
Senior Regulatory Affairs Associate
7475 Lusk Boulevard
San Diego, California 92121

JUL 15 2010

Re: K101284
Trade/Device Name: NuVasive® Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: May 06, 2010
Received: May 07, 2010

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 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,

For Peter D Rumm MPH
Dep D.R Rumm
DSORD

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): K101284

Device Name: *NuVasive® Facet Screw System*

Indications for Use:

The *NuVasive® Facet Screw System* is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The *NuVasive Facet Screw System* is indicated for facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1 (inclusive). The *Facet Screw System* is indicated for treatment of any or all of the following:

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(d) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies;
(e) degeneration of the facets with instability; and
(g) fracture.

The NuVasive *Facet Screw System* is intended for conventional or percutaneous surgical placement.

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 K101284