MAR 1 2 2002

## VII. 510(k) Summary

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

### A. Submitted by:

Laetitia Bernard
Manager of Regulatory Affairs and Quality Assurance
NuVasive™, Incorporated
10065 Old Grove Road
San Diego, California 92131
Telephone: (858) 527-1918
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### B. Device Name

Trade Name: NuVasive™ *Triad™ Facet Screw System*

Common or Usual Name: *Posterior Facet Screw and Washer*

Classification Name: *Facet Screw Spinal Device System*

### C. Predicate Devices

The subject NuVasive™ *Triad™ Facet Screw System* is substantially equivalent to the *NuVasive™ Percutaneous Transfacet/Intrapedicular Screw* currently manufactured and distributed commercially in the U.S. by NuVasive™, Inc.

### D. Device Description

The NuVasive™ *Triad™ Facet Screw System* consists of broad-headed, partially threaded screws designed to compact juxtaposed facet articular processes to enhance spinal fusion and stability. The non-threaded portion facilitates compression of the joint surfaces through a lag technique. Washers may be used to complement the screws by helping distribute forces and maintain consistent contact area when the screws are angled relative to the bone surface. The screws and washers are fabricated from anodized titanium alloy (Ti-6Al-4V) and are supplied in various sizes.

## E. Intended Use

The NuVasive™ *Triad™ Facet Screw System* is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The NuVasive™ *Triad™ Facet Screw System* is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1 for the 3.5mm screws, and from L1 to S1 for the 4.5mm screws. The *Triad™ 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
(i) fracture.

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

## F. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to the *NuVasive™ Percutaneous Transfacet/Intrapedicular Screw* cleared by the agency for commercial distribution in the United States.

Engineering drawings and labeling have demonstrated that the subject device is equivalent to the original device in terms of design, materials of composition, manufacturing, packaging, indications for use, and method of use, excepting only the fact that it may be implanted in conjunction with a washer, and may be available in a cannulated design in specific sizes.

Due to this equivalency, the device raises no new safety or effectiveness issues.

## G. Summary of Design Control Activities

Design control activities employed to control the development of the modification to the *NuVasive™ Transfacet/Intrapedicular Screw* included:

- a comprehensive Risk Analysis to identify potential risks and failures associated with operation of the device, any mitigations incorporated to reduce or eliminate those risks and failures, and an assessment of residual risk;
- a comprehensive program of verification and validation activities demonstrating that acceptance criteria were met, and that design output satisfied design input.

## H. Summary of Clinical Tests

(Not applicable.)

## I. Conclusions

The subject device is substantially equivalent to the currently marketed predicate device, and its development has been adequately and appropriately conducted and validated under a comprehensive design control program complying with Title 21 CFR, §820.30.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2002

Laetitia Bernard
Manager of Regulatory Affairs and Quality Assurance
NuVasive™, Incorporated
10065 Old Grove Road
San Diego, California 92131

Re: K020411
Trade/Device Name: NuVasive™ Triad™ Facet Screw System
Regulatory Number: unclassified
Regulation Name: N/A
Regulatory Class: II
Product Code: MRW
Dated: February 6, 2002
Received: February 7, 2002

Dear Ms. Bernard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Millar

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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**D. Indications for Use Statement**

510(k) Number (if known): ~~K020444~~ K020411

Device Name: *Triad™ Facet Screw System*

Indications for Use:

The NuVasive™ *Triad™ Facet Screw System* is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The NuVasive™ *Triad™ Facet Screw System* is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1 for the 3.5mm screws, and from L1 to S1 for the 4.5mm screws. The *Triad™ Facet Screw System* is indicated for treatment of any or all of the following:

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(g) fracture.

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

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K020411

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)