

APR 1 8 2000

VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and 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:

R. Stephen Reitzler
Vice President, Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
10065 Old Grove Road, Suite A
San Diego, California 92131
Telephone: (858) 271-7070
Telefacsimile: (858) 271-7101

B. Device Name

Trade or Proprietary Name: *Townley Transfacet/Intrapedicular Screw*
Common or Usual Name: Posterior Facet Screw
Classification Name: Class II

C. Predicate Devices

The subject device is the exact same device as the preamendment *Townley Bone Graft Screw* (also known as the *Townley Compression Screw*), which was marketed prior to May, 1976, by Zimmer Manufacturing Company.

D. Device Description

The *Townley Transfacet/Intrapedicular Screw* consists of a broad-headed, partially threaded screw 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 gliding hole technique. The screws are available fabricated from medical grade stainless steel (ASTM F-138) or Ti6Al4V alloy (ASTM F136 or 1472), and are supplied in various lengths ranging from 25 mm (approx. 0.98") to 60 mm (approx. 2.37"). In all sizes, the screws have a major diameter of 3.5 mm (approx. 0.140") and a minor diameter of 2.70 mm (approx. 0.106").

E. Intended Use

The *Townley Tranfacet/Intrapedicular Screw* 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 *Townley Screw* is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, and from C2 to S1, 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

F. Comparison to Predicate Devices

As was established in this submission, the subject device is exactly the same as the preamendment device marketed prior to May of 1976 by the Zimmer Manufacturing Company under the trade names Townley Bone Graft Screw and Townley Compression Screw, excepting only that it will be offered in MRI-compatible titanium alloy in addition to its preamendment stainless steel form.

Affidavits and commercial literature have established that the subject device is the same as the preamendment device in terms of its design, materials of composition, dimensions, indications for use, and method of use, as the preamendment device distributed commercially by Zimmer Manufacturing Company prior to May of 1976. As noted above, only the addition of an MRI-compatible form of the screw is different.

G. Summary of Non-Clinical Tests

Static and fatigue testing conducted in accordance with ASTM Standard F1717 indicate that the titanium form of the subject device has superior ultimate load than the stainless steel form of the device, with a higher percentage of the ultimate load at run-out in the fatigue testing.

H. Summary of Clinical Tests

(Not applicable.)

I. Conclusions of Non-Clinical and Clinical Tests

As recommended by the agency's Guidance for Spinal System 510(k)s, dated May of 1999, testing has been conducted to demonstrate conformance with ASTM Standard F1717, as applicable to the design of the device, and also with ASTM Standard E739.



APR 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steve Reitzler, RAC
Vice President, Regulatory Affairs and Quality Assurance
Nuvasive Inc.
10065 Old Grove Road, Suite A
San Diego, California 92131

Re: K994308/S1
Trade Name: Townley Transfacet/Intrapedicular Screw
Regulatory Class: II
Product Code: MRW
Dated: March 23, 2000
Received: March 24, 2000

Dear Mr. Reitzler:

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 control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

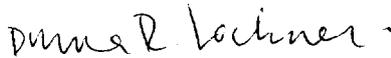
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 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

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K994308

Device Name: NuVasive, Inc., Townley Facet Screw

Indications for Use:

The Townley Tranfacet/Intrapedicular Screw 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 Townley Screw is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, and from C2 to S1, for treatment of any or all of the following:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
 Diane K. Rodner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994308
Over-The-Counter Use

Prescription Use OR
(Per 21 CFR 801.109)