VII. 510(k) Summary

K992782

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: NuVasive *Spinal Arthroscope*

Common or Usual Name: Arthroscope

Classification Name: Arthroscope

C. Predicate Devices

The subject device is substantially equivalent, in whole or in part, to one or more of the following predicate devices, among others:

Arthroscope (Henke-Sass, Wolf, GmbH)
PercScope™ (Clarus Medical)
Yeung Endoscopic Spine System (Richard Wolf)
Panoview Arthroscope (Richard Wolf)
Spine Endoscope (Endius)
Angled Neuroendoscope (AESCULAP®)
Neurological Endoscope (Richard Wolf)
Olympus Neuro Endoscope (Olympus Optical)
INCLUSIVE™ Endoscopic System (Sofamor Danek)

D. Device Description

The subject *Spinal Arthroscope* is a rigid diagnostic arthroscope with outer sheath. The diagnostic scope is available in three (3) models, consisting of arthroscopes with 0°, 30°, and 70° viewing angles, each of which has a working length of 400 $\pm$0.5 mm. The field of view for each is 105°.

The device employs a rod lens imaging system and a fiberoptic light guide for illumination. The standard eyepiece permits use of the subject device with various commercially-available video systems. While the device is manufactured with an ACMI-type illumination sidearm, it is supplied with both Richard Wolf-, and Storz-type adaptors which permit connection to many commercially-available light sources. The outer sheath has a 5.0 mm outer diameter and is equipped with a standard luer lock stopcock to permit irrigation through the sleeve. The subject *Spinal Arthroscope* is provided non-sterile, and is reusable.

E. Intended Use

The NuVasive *Spinal Arthroscope*, consisting of a rigid diagnostic arthroscope with an outer sheath, is intended to achieve percutaneous vizualization of, and/or to assist in performing percutaneous surgical procedures on, the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via biportal posterior or posterolateral approach, where anatomic restrictions permit percutaneous access. The device is intended for use in conjunction with the NuVasive *Guided Spinal Arthroscopy System* under real-time radiographic visualization via image-intensified C-arm fluoroscopy, but may be employed independent of that system where it is compatible in diameter and length with commercially available arthroscopic instrumentation, and with surgical need.

F. Comparison to Predicate Devices

The subject device has indications for use which are substantially equivalent to those of one or more of the predicate devices, is composed of the same or equivalent materials as one or more of the predicate devices, has the same design features as one or more of the subject devices, and has functional characteristics which are the same or equivalent to those of one or more of the predicate devices. Due to the equivalency of indications for use, materials of composition, design features, method of use, and functional characteristics, the device raises no new safety or effectiveness issues.

G. Summary of Non-Clinical Tests

(Not applicable.)

H. Summary of Clinical Tests

(Not applicable.)

I. Conclusions of Non-Clinical and Clinical Tests

(Not applicable.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1999

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

Re: K992782
Trade Name: Spinal Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: August 17, 1999
Received: August 19, 1999

Dear Mr. Reitzler:

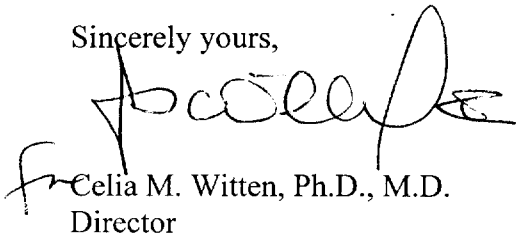
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4595. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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): K992782

Device Name: NuVasive, Inc., Spinal Arthroscope

Indications for Use:

The NuVasive *Spinal Arthroscope*, consisting of a rigid diagnostic arthroscope with outer sheath, is intended to achieve percutaneous vizualization of, and/or to assist in performing percutaneous surgical procedures on, the spinal nerve root, foramina, intervertebral disc, and the surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomic restrictions permit percutaneous access. The device is intended for use in conjunction with the NuVasive *Guided Spinal Arthroscopy System* under real-time radiographic visualization via image-intensified C-arm fluoroscopy, but may also be employed independent of that system where it is compatible in diameter and length with other commercially available arthroscopic instruments, and with surgical need.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992782

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109)