

K990324

**VII. 510(k) Summary**

In accordance with the Safe Medical Devices Act (SMDA) of 1990, and Title 21 of the Code of Federal Regulations (21 CFR), Part 807, and in particular §807.92, the following summary of safety and effectiveness information is provided:

**A. Submitted by**

R. Stephen Reitzler, RAC  
Voce President, Regulatory Affairs & Quality Assurance  
NuVasive, Incorporated  
10065 Old Grove Road, Suite A  
San Diego, California 92131

**B. Device Name**

Trade or Proprietary Name:	Guided Spinal Arthroscopy System
Common or Usual Name:	Arthroscope accessories
Classification Name:	Arthroscope [and accessories]

**C. Predicate Devices**

The subject device is substantially equivalent to the following predicate devices, among others:

INCLUSIVE™ Endoscope and Micro-Endo™ Instruments (Sofamor Danek)  
PercScope™ (Clarus Medical)  
Percutaneous Discectomy System (Richard Wolf Medical)  
Gouda Stereotactic Frame (neurological Devices)  
Stereoguide Breast Biopsy System (Lorad Corp.)  
ABBI™ System and Auto Suture® Dilating Cannula (U.S. Surgical Corp.)  
Mammotome Multi-Probe (Biopsys Medical)  
ENDOPATH™ Trocar Sleeve with Dilating Obturator (Ethicon)

**D. Device Description**

The subject System consists of a rigid instrument guide frame adjustable in multiple dimensions and planes, a series of expanding tip cannulae which can be introduced with precision to the operative site through the guide frame, and related manual arthroscopic instruments. Under radiographic guidance, the System assists the physician in gaining controlled, percutaneous access to the spine and adjacent tissues and structures, via uniportal or biportal approach.

**E. Intended Use**

The NuVasive *Guided Spinal Arthroscopy System* consists of a rigid instrument Guide Frame with adjustable cannula guides, and various arthroscopic cannulae and instrumentation. The *System* is intended to assist in gaining controlled percutaneous access to, and visualization of, the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomical restrictions safely permit. It is intended for use under real-time, or near real-time (i.e., successive static image) radiographic visualization via image-intensified C-arm fluoroscopy. The System is designed for use with the NuVasive *Spinal Arthroscope*, but may be used with other arthroscopes having a minimum working length of 400 mm, an outer sheath diameter of 5.0 mm, and which are indicated for use in the spine.

**F. Comparison to Predicate Devices**

The subject device has substantially equivalent indications for use as one or more of the predicate devices, being intended to provide controlled and precise alignment, orientation, and introduction of arthroscopic instruments to the spine, using a rigid guide frame and radiographic guidance;

The subject device is composed of the same or equivalent materials as one or more of the predicate devices, all of which are established as safe for their application in the subject device;

The subject device encompasses design features which are substantially equivalent to those offered by one or more of the predicate devices, including adjustment of the frame in multiple angles and planes under radiographic guidance to optimize surgical approach angles, an expanding cannula tip, and a selection of instrument and cannula diameters;

The System provides functions equivalent to those provided by one or more of the predicate devices, serving to establish a port of entry to the spine and adjacent tissues for the introduction and use of arthroscopic instrumentation in diagnostic and interventional percutaneous spinal procedures;

Further, the subject device is packaged and labeled in a manner substantially equivalent to one or more of the predicate devices.

**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)



OCT 5 1999

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: K990324  
Trade Name: NuVasive Guided Spinal Arthroscopy System  
Regulatory Class: II  
Product Code: HRX  
Dated: July 2, 1999  
Received: July 7, 1999

Dear Mr. Reitzler:

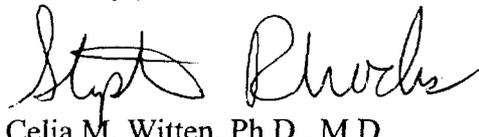
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,

*for* 

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

**V. Draft Labeling**

**A. Indications for Use**

510(k) Number (if known):  K990324

Device Name: NuVasive, Inc., Guided Spinal Arthroscopy System

Indications for Use:

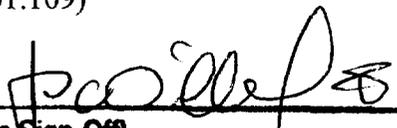
The NuVasive *Guided Spinal Arthroscopy System* consists of a rigid instrument Guide Frame with adjustable cannula guides, and various arthroscopic cannulae and instrumentation. The *System* is intended to assist in gaining controlled percutaneous access to, and visualization of, the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomical restrictions safely permit. It is intended for use under real-time, or near real-time (i.e., successive static image) radiographic visualization via image-intensified C-arm fluoroscopy. The System is designed for use with the NuVasive *Spinal Arthroscope*, but may be used with other arthroscopes having a minimum working length of 400 mm, an outer sheath diameter of 5.0 mm, and which are indicated for use in the spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-the-Counter Use

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number  K990324