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:

Lactitia Bernard
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
10065 Old Grove Road
San Diego, California 92131
Telephone: (858) 271-7070
Telefacsimile: (858) 271-7101

B. Device Name

Trade or Proprietary Name:	*NuVasive NeuroVision JJB System*
Common or Usual Name:	Electromyography (EMG) monitor/stimulator
Classification Name:	Surgical nerve stimulator/locator
Device Class:	Class II
Classification:	§874.1820, §882.1870
Product Code:	77ETN, 84GWF

C. Predicate Devices

The subject *NeuroVision JJB System* is substantially equivalent to the *NeuroVision JJB System* currently manufactured and distributed commercially in the U.S. by NuVasive.

D. Device Description

The *NVJJB System* utilizes conventional neurophysiologic monitoring to reduce the incidence of injury to nerve roots during instrumented spine surgery. In the procedure, stimulus evoked electromyography is used to determine changes in nerves. Corresponding muscle groups are monitored using surface electrodes, while stimulation is used to detect nerve responses.

The NeuroVision JJB System consists of a reusable Patient Module, a Control Unit comprised of an embedded computer with touch screen controls and an interface card, and an assortment of disposable and reusable conductive probes, electrodes, and electrode leads.

E. Intended Use

The NeuroVision JJB System is intended to provide stimulation of spinal nerves during surgery of the spine, and intraoperative electromyographic (EMG) nerve surveillance to assist, by administration of brief electrical stimulus pulses to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves, in the following: a) Location and evaluation of spinal nerves, using the System's Screw Test, Detection, and/or Free Run EMG Functions; and b) Location and identification of spinal nerves, using the System's Nerve Retraction Function.

The NeuroVision JJB System is designed for use in conjunction with other NuVasive devices to assist in gaining controlled access to, and visualization of, the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal approach, where anatomical restrictions safely permit.

F. Comparison to Predicate Devices

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation. Due to this equivalency, the device raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Ms. Laetitia Bernard
Director of Regulatory Affairs
and Quality Assurance
NuVasive, Inc.
10065 Old Grove Road
San Diego, California 92131

Re: K040543
Trade/Device Name: NuVasive NeuroVision JJB System
Regulation Number: 21 CFR 874.1820, 21 CFR 890.1375
Regulation Name: Surgical nerve stimulator/locator, diagnostic electromyograph
Regulatory Class: II
Product Code: ETN, GWP
Dated: March 1, 2004
Received: March 2, 2004

Dear Ms. Bernard:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K040543

Device Name: NeuroVision JJB System

Indications For Use:

The NeuroVision JJB System is intended to provide stimulation of spinal nerves during surgery of the spine, and intraoperative electromyographic (EMG) nerve surveillance to assist, by administration of brief electrical stimulus pulses to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves, in the following: a) Location and evaluation of spinal nerves, using the System's Screw Test, Detection, and/or Free Run EMG Functions; and b) Location and identification of spinal nerves, using the System's Nerve Retraction Function.

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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)

Miriam C. Provost

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

510(k) Number K040543