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K002677

Section VII

510(k) Summary

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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, RAC
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: *INS-1 Introperative Nerve Surveillance System*

Common or Usual Name: *Electromyography (EMG) monitor/stimulator*

Classification Name: *Surgical nerve stimulator/locator*

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:

Brackmann II™ EMG Monitoring System (WR Medical Electronics Co.)
Neurovision SE Nerve Locator/Monitor (RLN Systems, Inc.)
Viking IV™ Electromyography System (Nicolet Biomedical)
Epoch 2000 Neurological Workstation (Axon Systems, Inc.)
Neurosign 400 Motor Nerve Monitor (Magstim Company, Ltd.)

D. Device Description

The subject *INS-1 System* is an electronic device which uses arthroscopic surgical instruments, electrodes, and probes to stimulate spinal nerves with electrical energy, and through the use of electromyography (EMG) electrodes, monitors the sensitivity, and assists in determining the location, of spinal nerves during percutaneous surgery of the spine.

The device employs a "Status" routine to determine the baseline functional status of exiting spinal nerves in the area of the operative target, and directs low amperage current through the distal tip of the NuVasive *Expanding Cannula* as it penetrates tissue to the operative target.

Through a series of EMG electrodes placed on the muscle groups associated with the spinal nerves at the operative level of the spine, the *INS-1 System* monitors EMG activity in these muscle groups and, when the Cannula tip draws sufficiently near to one such nerve that the electrical energy it emits is strong enough to depolarize the nerve and create an EMG response, alerts the surgeon that the Cannula tip is in proximity to that nerve.

An additional feature of the *INS-1 System* is a hand-held electrical probe which can assist the surgeon in determining if a nerve lies directly in the path of the instrumentation, and may also be used to ascertain whether a transpedicular screw has violated the pedicle wall.

The *INS-1 System* consists of a reusable Control Unit and PreAmp module, and an assortment of disposable and reusable conductive probe cables, electrodes, and electrode leads.

E. Intended Use

The *INS-1 Intraoperative Nerve Surveillance System* is intended to provide intraoperative electromyographic (EMG) surveillance to assist in the location and evaluation of spinal nerves during percutaneous surgery of the spine, by administration of low amperage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves. The *INS-1 System* is designed for use in conjunction with the NuVasive *Guided Spinal Arthroscopy System* to assist in gaining controlled percutaneous access to 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.

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 commercially marketed devices, has the same design features as one or more of the predicate 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

Animal studies conducted in the porcine model have established that 1) the principle functions of the *INS-1 System* are effectively performed, such that spinal nerve status and location may be ascertained and monitored, and 2) that the data acquired by the subject device during simulated surgical use in the animal model correlate well with those acquired simultaneously by a predicate device.

H. Summary of Clinical Tests

(Not applicable.)

I. Conclusions of Non-Clinical and Clinical Tests

The subject device is substantially equivalent in function to that of at least one predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2000

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

Re: K002677
Trade Name: NuVasive INS-1 Intraoperative Nerve Surveillance System
Regulatory Class: II
Product Code: BXM
Dated: August 24, 2000
Received: August 28, 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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may

result in regulatory action. In addition, the Food and Drug Administration (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 the 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K002677

Device Name: NuVasive *INS-1 Intraoperative Nerve Surveillance System*

Indications for Use:

The *INS-1 Intraoperative Nerve Surveillance System* is intended to provide intraoperative electromyographic (EMG) surveillance to assist in the location and evaluation of spinal nerves during percutaneous surgery of the spine, by administration of low amperage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves. The *INS-1 System* is designed for use in conjunction with the NuVasive *Guided Spinal Arthroscopy System* to assist in gaining controlled percutaneous access to 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

for Mark A. Milhouse
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002677