K090298

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:

Ms. Han Fan
Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1868
Fax: (858) 909-2068

JUN - 8 2009

B. Device Name

Trade or Proprietary Name:	*NuVasive® NeuroVision® EMG Endotracheal Tube*
Common or Usual Name:	Endotracheal Tube with Electromyography (EMG) monitoring Electrodes.
Classification Name:	Tracheal Tube Inflatable Cuff Surgical nerve stimulator/locator
Device Class:	Class II
Classification:	§874.1820, §882.1870, §868.5730 and §868.5750
Product Code:	ETN, GWF

C. Predicate Devices

The subject *NeuroVision EMG Endotracheal Tube* is substantially equivalent to the *Xomed EMG Endotracheal Tube* and the *Arcadia Medical Endotracheal Tube* currently distributed commercially in the U.S..

D. Device Description

The *NeuroVision® EMG Endotracheal (ET) Tube* is a low pressure cuff endotracheal tube with integrated electrodes for electromyographic (EMG) monitoring during surgery.

E. Intended Use

The *NeuroVision® EMG Endotracheal Tube* is intended for use with any compatible monitoring system during surgical procedures for continuous EMG neurological monitoring and status assessment of the nerves supplying the laryngeal musculature as well as for providing an open airway for patient ventilation.

F. Substantial Equivalence

As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.

Engineering specifications and labeling have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NuVasive, Inc.
c/o Han Fan
Regulatory Affairs Associate
7475 Lusk Blvd.
San Diego, CA 92121

JUN - 8 2009

Re: K090298
Trade/Device Name: NuVasive® NeuroVision® EMG Endotracheal Tube
Regulation Numbers: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: II
Product Code: GWF
Dated: May 21, 2009
Received: May 22, 2009

Dear Ms. Fan:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090298

Indications for Use

510(k) Number (if known): K090298

Device Name: NuVasive NeuroVision EMG Endotracheal Tube

Indications For Use:

The NeuroVision EMG Endotracheal Tube is intended for use with any compatible monitoring system during surgical procedures for continuous EMG neurological monitoring and status assessment of the nerves supplying the laryngeal musculature as well as for providing an open airway for patient ventilation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

CG

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090298