510(k) Summary

MAY 0 2 2014

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Jeremy Markovich
Associate Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: April 25, 2014

B. Device Name

Trade or Proprietary Name:	*NuVasive® EMG Endotracheal Tube*
Common or Usual Name:	Neurosurgical Nerve Locator; Endotracheal Tube with Electromyography (EMG) monitoring Electrodes
Classification Name:	Surgical nerve stimulator/locator; Tracheal Tube; Inflatable Cuff;
Device Class:	Class II
Classification:	§874.1820, §882.1870, §868.5730 and §868.5750
Product Code:	PDQ, ~~EXN, GWF~~ BSK and BTR

C. Predicate Devices

The subject *NuVasive EMG Endotracheal Tube* is substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K094054 – NuVasive NV EMG Endotracheal Tube

D. Device Description

The *NuVasive® EMG Endotracheal (ET) Tube* is an endotracheal tube with integrated electrodes for electromyographic (EMG) monitoring during surgery. The ET tube is made of a flexible PVC material with an inflatable low pressure cuff. The *EMG ET Tube* is provided as a sterile, single use disposable accessory that connects to a compatible EMG monitor to provide an open airway for patient ventilation during EMG neuromonitoring of the Recurrent Laryngeal Nerve (RLN).

E. Intended Use

The *NuVasive 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. Technological Characteristics

As was established in this submission, the subject *NuVasive EMG Endotracheal Tube* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, packaging, and sterilization. This device does not contain software. See the table below for a detailed comparison:

	Predicate Devices	**Subject Device**
	NuVasive NV EMG Endotracheal Tube (K094054)	**NuVasive EMG Endotracheal Tube**
Laryngeal Surface Electrode	YES	YES
Endolaryngeal Location	YES	YES
Number of Electrodes	2 bipolar	2 bipolar
Electrode Surface Material	Conductive Silver Ink	Conductive Silver Ink with PVC Base
Tube & Cuff Materials	PVC	PVC (Non-DEHP)
Reinforcing Material	None	None
Tube Dimensions	Various Dimensions	Various Dimensions
Sterilization & Packaging	Sterile, single use only	Sterile, single use only

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NuVasive EMG Endotracheal Tube* is substantially equivalent to other predicate devices. The following testing was performed:

- Biocompatibility testing per ISO 10993-1 requirements, including:

Test Name	**Results**	**Conclusion**
Cytotoxicity testing – MEM Elution	Discrete intracytoplasmic granules; no cell lysis (Grade 0)	Pass Non-cytotoxic
Intracutaneous testing – NS and CSO	No erythema (Score 0) No edema (Score 0)	Pass Requirements met
Sensitization testing – NS and CSO	No sensitization observed (Score 0)	Pass Non-sensitizer
Systemic toxicity – NS and CSO	No signs or symptoms of systemic toxicity observed	Pass Requirements met

- Functional bench testing, including:
  - Functional testing per ISO 5361
  - inflation valve functionality
  - leak test
  - electrode resistance test
  - system integration test
  - bending test
- Stability Testing
- Sterilization & Packaging Validations

The results of these studies showed that the modified device meets the same specifications and criteria as the predecessor predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NuVasive EMG Endotracheal Tube* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

NuVasive, Incorporated
Mr. Jeremy Markovich
Associate Manager, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

Re: K133530
Trade/Device Name: NuVasive® EMG Endotracheal Tube
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ, BSK and BTR
Dated: March 31, 2014
Received: April 1, 2014

Dear Mr. Markovich:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133530

Device Name
NuVasive EMG Endotracheal Tube

Indications for Use *(Describe)*

The NuVasive 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.02 11:22:42 -04'00'

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