510(k) Summary

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:

Elias Ketchum
Senior Associate, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Contact: (858) 320-4588

Date Prepared: September 2, 2011

B. Device Name

Trade or Proprietary Name:	*NuVasive® Stimulation/Dissection Instruments*
Common or Usual Name:	Nerve Stimulator/Locator
Classification Name:	Surgical Nerve Stimulator/Locator

Device Class:	Class II
Classification:	21 CFR § 874.1820
Product Code:	ETN

C. Predicate Devices

The subject *Stimulation/Dissection Instruments* are substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K031003 – Medtronic Stimulation/Dissection Instruments
- K111597 – NuVasive Disposable Stimulating Electrode

D. Device Description

The *NuVasive Stimulation/Dissection Instruments* are similar to existing Class I exempt manual surgical instruments described in 21 CFR 88.4540 Orthopedic Manual Surgical Instruments. The instruments consist of retractors, dilators (expanding set of cannula), a stimulating electrode, taps, drills, probes, needles, and screw drivers with proximal connectors to attach the instruments to a monopolar stimulator, and insulating sheaths to provide biocompatible electrical insulation to selected portions of the instruments. The distal surfaces of the instruments are selectively non-insulated and manufactured from durable biocompatible materials to provide for mechanical, manual dissection/resection, probing, and tissue stimulation.

E. Intended Use

The Stimulation/Dissection Instruments are indicated for tissue dissection and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

F. Technological Characteristics

As was established in this submission, the subject *Stimulation/Dissection Instruments* are 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, and functions.

Predicate and Subject Device Comparison Table

Characteristics	Predicate Device	Subject Device	Substantially Equivalent
	Stimulation/Dissection Instruments K031003	**NuVasive® Stimulation/Dissection Instruments K112709**	
Indications for Use	The Stimulation/Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	The Stimulation/Dissection Instruments are indicated for tissue dissection and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	**Yes**
Product Code	ETN	ETN	**Yes**
21 CFR	874.1820	874.1820	**Yes**
Electrical Insulation	Electrical insulation on all surfaces not intended to provide electrical contact with the patient and connection	Some instruments have electrical insulation on surfaces not intended to provide electrical contact with the patient and connection while others are used with an insulating accessory that provides electrical insulation on surfaces not intended to provide electrical contact with the patient and connection.	**Yes**
Proximal Stimulator Connector	Yes	Yes	**Yes**
Patient Contact Material	Biocompatible	Biocompatible: Anodized Aluminum Stainless Steel Radel	**Yes**
Use and Delivery	Sterile for single use	Some instruments are provided sterile for single use only while others are provided as non-sterile reusable instruments.	**Yes**

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *Stimulation/Dissection Instruments* are substantially equivalent to other predicate devices. The following testing was performed:

- Stimulation and Insulation Impedance
- Current Density Determination
- Biocompatibility testing per ISO 10993-1
- Sterilization validation per ISO 11135-1

The results of these studies showed that the subject *Stimulation/Dissection Instruments* meets or exceeds the performance of the 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 *Stimulation/Dissection Instruments* has been shown to be substantially equivalent to legally marketed predicate devices, and do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NuVasive, Inc.
c/o Mr. Elias Ketchum
Senior Associate, Regulatory Affairs
7475 Lusk Blvd.
San Diego, California 92121

FEB - 9 2012

Re: K112709
Trade/Device Name: NuVasive Stimulation/Dissection Instruments
Regulation Number: 21 CFR 874.1820
Regulation Name: Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: January 6, 2012
Received: January 9, 2012

Dear Mr. Ketchum:

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 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/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 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.

Sincerely yours,

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

Enclosure

K112709

Indications for Use

510(k) Number (if known): K112709

Device Name: *NuVasive® Stimulation and Dissection Instruments*

Indications For Use:

The Stimulation/Dissection Instruments are indicated for tissue dissection and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

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)

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

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K112709