K072343

5. 510(K) SUMMARY

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Laetitia Cousin
Director of Regulatory Affairs and Quality Assurance
NuVasive, Incorporated
4545 Towne Centre Court
San Diego, California 92121
Telephone: (858) 909-1868
Fax: (858) 909-2068

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 device is substantially equivalent to the following previously cleared devices.

Trade or Proprietary Name:	NuVasive NeuroVision JJB System
Manufacturer:	NuVasive, Inc.
Classification Name:	Surgical nerve stimulator/locator
Device Class:	Class II
Classification:	§874.1820, §882.1870
Product Code:	77ETN, 84GWF
510(k) Number:	K062765

Trade or Proprietary Name:	DS7A Constant Current High Voltage Stimulator
Manufacturer:	Digitimer, LTD
Classification Name:	Stimulator, Electrical, Evoked Response
Device Class:	Class II
Classification:	§882.1870
Product Code:	84GWF
510(k) Number:	K051357

Trade or Proprietary Name:	Epoch XP
Manufacturer:	Axon Systems
Classification Name:	Electroencephalograph
Device Class:	Class II
Classification:	§882.1400
Product Code:	GWQ, GWE, GWF, GWJ
510(k) Number:	K032741

D. Device Description

The NeuroVision JJB System consists of a 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 System is intended for use in the operating room and non-critical care clinical environment for neurological monitoring and status assessment. The System may be used alone or in conjunction with other NuVasive devices to assist in gaining controlled access to the spine.

F. Substantial Equivalence

Data was provided which demonstrated the NuVasive NeuroVision JJB to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material, and function.

G. Summary of Non-Clinical Tests

(Not Applicable).

H. Summary of Clinical Tests

(Not Applicable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2007

Nuvasive, Inc.
% Ms. Laetitia Cousin
4545 Towne Centre Court
San Diego, California 92121

Re: K072343
Trade/Device Name: Neurovision JJB System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: August 20, 2007
Received: August 21, 2007

Dear Ms. Cousin:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
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): K072343

Device Name: NeuroVision® JJB System

Indications For Use:

The NeuroVision System is intended for use in the operating room and non-critical care clinical environment for neurological monitoring and status assessment. The System may be used alone or in conjunction with other NuVasive devices to assist in gaining controlled access to the spine.

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)

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

510(k) Number K072343