K110696

JUL - 7 2011

BAXANO

510(k) Summary

Submitter Identification

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Date Prepared June 30, 2011

Device Name

Proprietary Name	Neuro Check™ Device with iO-Flex™ Wire
Common Name	Nerve locator
Classification Name	Surgical nerve stimulator/locator
Classification	21 CFR §874.1820
Device Class	Class II
Product Code	ETN

Predicate Device

The modified Neuro Check Device is substantially equivalent to one or more of the following predicate devices listed in **Table 1** below:

Predicate Device	Product Code	510(k) Number	Clearance Date
Baxano Neuro Check™ Device	ETN	K092729	10/02/2009
NuVasive NeuroVision JJB and M5 System and Probes	GWF	K062765	01/24/2007
Medtronic NIM Eclipse and Probes (formerly Axon Systems OrthoMon System)	GWF, IKN	K061113	05/23/2006
Cadwell Sierra Wave EMG/NCV/EP	GWF	K924723	03/23/1993

Device Description

Neuro Check™ Device with iO-Flex™ Wire are provided sterile and disposable after single-patient use.

The Neuro Check Device is designed to be pulled into the neural foramen by the iO-Flex Wire to enable the surgeon to direct a stimulus signal from a commercial EMG system to electrodes on the device enabling nerve root location prior to using a Baxano cutting and biting device. The Neuro Check Device is manufactured from biocompatible Pebax® tubing and stainless steel with a handle molded from ABS. The proximal end of the device handle has a pair of wires that connect to commercially available EMG systems.

The iO-Flex Wire is manufactured from nickel-titanium wire and connects to the distal end of the Neuro Check Device for placement in the neural foramen. No changes were made to the previously cleared iO-Flex Wire design (K100958) other than packaging modifications to include it within the Neuro Check Device packaging for surgeon convenience.

Since the previous clearance of the Neuro Check Device (K092729; October 2, 2009) changes were made to the physician labeling (the Instructions For Use) intended to provide compatibility with enhanced output stimulus signals of commercially-available intra-operative electromyography (EMG) neuromonitoring systems for motor nerve localization. Specifically, the maximum allowable EMG stimulation current amplitude to the Neuro Check Device was increased from 30 milliamps to 50 milliamps and the maximum current pulse width from 300 microseconds to 500 microseconds to support the stimulation parameters of commercially available EMG systems. There were no design modifications of the Neuro Check Device necessary to conform to the new electrical stimulation specifications.

In addition, several design modifications were implemented since the last Neuro Check Device clearance. These modifications include integrating the separate Switch Box into the Neuro Check Device handle, eliminating the need for this external accessory. The handle itself is now molded from ABS plastic instead of being machined from the same material. Two radiopaque platinum-iridium marker bands were added to the distal flexible section to assist with fluoroscopic positioning of the device. A slight bend is made in the distal flexible segment to assist in orienting the Neuro Check

Device as it is positioned with respect to the patient. Lastly, the iO-Flex Wire was added to the Neuro Check Device package for user convenience.

Intended Use

The Baxano Neuro Check™ Device is intended for use with an iO-Flex™ cutting and biting device for location of motor nerves in settings where visualization is compromised.

Technological Characteristics and Substantial Equivalence

The modified Neuro Check Device with iO-Flex Wire is substantially equivalent to the predicate Neuro Check Device (K092729) and the iO-Flex Wire (K100958). No changes were made to the previously cleared iO-Flex Wire design other than packaging modifications to include it with the Neuro Check Device for surgeon convenience. The Neuro Check Device with iO-Flex Wire has the same indications for use and fundamental scientific technology as its predicate.

Modification of the Neuro Check Device labeling allows for an increase in maximum EMG stimulation current to 50 milliamps (from 30 milliamps) and maximum pulse width to 500 microseconds (from 300 microseconds). This change provides compatibility with the range of settings typically associated with EMG intraoperative neuromonitoring systems and enhances the surgeon's ability to elicit an EMG response in patients whose nerves are less responsive to electrical stimulus. The predicate NuVasive NeuroVision M5 System and Probes (K062765) and Cadwell Sierra Wave EMG System (K924723) are cleared for stimulation current of 0-100 milliamps. The Cadwell Sierra Wave EMG System (K924723) is cleared for a stimulation pulse width of up to 1000 microseconds.

Based upon the indications for use, technological characteristics and performance test results, changes to the Neuro Check Device with iO-Flex Wire do not raise new questions of safety or effectiveness.

A summary of the Neuro Check Device technological characteristics compared to the legally marketed predicate devices is provided in ***Table 2 and 3*** below.

Table 2. Physical Attributes

Attribute	Modified Neuro Check Device (K110696)	Predicate Neuro Check Device (K092729)	Change
Shaft Length	4.5 inches	4.6 inches	Equivalent
Handle Length	6 inches	2 inches	Handle is longer to accommodate switching
Lead Length	152 inches	Probe cable: 72 inches Twisted Wire Cable: 80 Inches	No change in total lead length
Tip Diameter/ Exposure	0.06 inches	0.06 inches	No change
Shaft Material	304 Stainless Steel	304 Stainless Steel	No change
Shaft Insulation	Pebax	Pebax	No change
Handle Material	ABS	ABS	No change
Lead Wire Material	28AWG Stranded Copper	Probe cable:28AWG Tinned Copper Twisted Wire Cable: 28AWG Stranded Copper	No change (Probe cable is obsolete)
Lead Wire Insulation	PVC	Probe cable: FEP medical grade Twisted Wire Cable: PVC	No change (Probe cable is obsolete)
Active surface area	0.018 square inches	0.018 square inches	No change
Dimensions of electrodes	Rectangular shaped: 0.022 inches width x 0.069 inches length	Rectangular shaped: 0.022 inches width x 0.069 inches length	No change
Number of electrodes	12 (6 on white side, 6 on black side)	12 (6 on white side, 6 on black side)	No change
Distance between electrode pair	0.040 inches	0.042 inches	Equivalent

Table 3. Substantial Equivalence Comparison Table

Feature / Technological Characteristic	Modified Baxano Neuro Check Device (K110696)	Baxano Neuro Check Device (K092729)	NuVasive NeuroVision JJB and M5 Systems (K062765)	Medtronic NIM-Eclipse (K061113)	Cadwell Sierra Wave EMG/NCV/EP (K924723)
Intended Use / Indications for Use	The Baxano Neuro Check Device is intended for use with an iO-Flex cutting and biting device for location of motor nerves in settings where visualization is compromised.	For use with Baxano iO-Flex cutting and biting devices for localization of motor nerves in settings where visualization is compromised.	The NeuroVision JJB System is used for intraoperative monitoring and neurological status assessment by the administration of brief electrical stimulus pulses to neural tissues and the EMG monitoring of the associated muscle groups. The System is used in conjunction with other NuVasive devices to assist in gaining controlled access to, and visualization of the spine.	The OrthoMon system is intended for use to record, monitor and stimulate/record biopotential signals including electromyograph (EMG), evoked response and nerve/muscle potentials and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at risk nerve roots.	Unable to locate; not available on FDA's web site.
Device Class	II	II	II	II	II
Product Code	ETN	HAE and ETN	GWF	GWF, IKN	GWF
Regulation Number	21 CFR 874.1820	21 CFR 882.4840 21 CFR 874.1820	21 CFR 882.1870	21 CFR 882.1870 21 CFR 890.1375	21 CFR 882.1870

Feature / Technological Characteristic	Modified Baxano Neuro Check Device (K110696)	Baxano Neuro Check Device (K092729)	NuVasive NeuroVision JJB and M5 Systems (K062765)	Medtronic NIM-Eclipse (K061113)	Cadwell Sierra Wave EMG/NCV/EP (K924723)
Clearance Date		10/02/2009	01/24/2007	05/23/2006	03/23/1993
Device Classification Name	Surgical Nerve Stimulator / Locator (ETN)	Surgical Nerve Stimulator / Locator (ETN)	Stimulator, Electrical, Evoked Response	Stimulator, Electrical, Evoked Response	Stimulator, Electrical, Evoked Response
Surgical Procedure	Minimally invasive procedures involving the spinal column where visualization is compromised	Minimally invasive procedures involving the spinal column where visualization is compromised	Minimally invasive procedures involving the spinal column where anatomical restrictions safely permit use.	Procedures that involve nerve location and mapping; including spinal surgery.	Procedures that involve nerve location and mapping.
Stimulation Probes	Monopolar and Bipolar	Monopolar and Bipolar	Monopolar	Monopolar and Bipolar	Unknown
Stimulation Current Amplitude	0 mA - 50 mA	0 mA - 30 mA	0 mA - 80 mA JJB 0 mA - 100 mA M5	0 mA - 50 mA	0-100 mA
Stimulation Current Pulse Width	150 – 500 µsec	150 – 300 µsec	200 µsec	50- 300 µsec	50 – 1000 µsec
Stimulation Current Frequency	3.0 – 5.0 Hz	3.0 – 5.0 Hz	5.0 Hz (standard)	Supports Stimulation Frequency 1- 10 Hz	Supports Stimulation Frequency up to 50 Hz
Power	Passive: To be used in conjunction with standard EMG monitoring systems	Passive: To be used in conjunction with standard EMG monitoring systems	AC Power	AC Power	AC Power

Feature / Technological Characteristic	Modified Baxano Neuro Check Device (K110696)	Baxano Neuro Check Device (K092729)	NuVasive NeuroVision JJB and M5 Systems (K062765)	Medtronic NIM-Eclipse (K061113)	Cadwell Sierra Wave EMG/NCV/EP (K924723)
Probe Patient Contact Materials	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-40	UL 60601-1 IEC 60601-1-2 CAN/CSA C22.2#601.1 IEC 60601-2-40	Information not publically available	IEC 60601-1 protected pin design EN/IEC 60601-1-2	UL2601-1, CSA601-1, EN60601-1 EN60601-1-1 EN60601-2-40 EN60601-1-1-2
Sterilization	E-beam	E-beam	EtO for reusable probes; unknown for disposable	EtO for reusable probes; unknown for disposable	Unknown
Software	None	None	Proprietary	Proprietary	Proprietary / Optional

Non-Clinical Tests

Mechanical performance tests were conducted to verify that the device meets design specifications and performance characteristics, based upon the intended use. The modified Neuro Check Device was subjected to electrical safety and compatibility testing and was certified to following standards, including all applicable normative reference standards:

- **IEC 60601-1: 1988 +A1:1991 +A2:1995** Medical Electrical Equipment Part 1: General Requirements for Safety
- **IEC 60601-2-40: 1998** Medical Electrical Equipment Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
- **IEC 60601-1-2: 2001 + A1:2004** Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility

Sterilization Data

The Neuro Check Device with iO-Flex Wire is sterilized by electron beam irradiation, identical to the method used by the predicate Neuro Check Device and the iO-Flex Wire (K081742, K092729 and K100958). The sterilization process has been validated by an approved contract facility to provide a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11137-1:2006 and ISO 11137-2:2006. The device is not labeled as non-pyrogenic.

Conclusions

Baxano has determined that the non-clinical and sterilization testing demonstrate that the modified Neuro Check Device with iO-Flex Wire is as safe, as effective, and performs as well as the legally marketed predicated devices.

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

Baxano, Incorporated
c/o Mr. Edward Sinclair
Vice President, Clinical Regulatory & Quality Affairs
655 River Oaks Parkway
San Jose, California 95134

JUL - 7 2011

Re: K110696
Trade/Device Name: Neuro Check Device with iO-Flex Wire
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: May 24, 2011
Received: May 25, 2011

Dear Mr. Sinclair:

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,

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

Indications for Use

510(k) Number (if known): K110696

Device Name: **Baxano Neuro Check™ Device with iO-Flex™ Wire**

Indications For Use:

The Baxano Neuro Check™ Device is intended for use with an iO-Flex cutting and biting device for location of motor nerves in settings where visualization is compromised.

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

510(k) Number K110696