K081742

SEP 1 7 2008

510(K) SUMMARY (21 CFR 807.92)

NEURAL LOCALIZATION PROBE

510(k) Owner: Baxano, Inc.
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Date Prepared: June 18, 2008

Trade Name: Baxano Neural Localization Probe

Common Name: Surgical nerve stimulator/locator

Classification: Nerve stimulation device (per 21 CFR section 874.1820)
Probe for skull or spinal column (per 21 CFR section 882.4840)

Predicate Devices: Baxano Standard Probe (K080494), Medtronic Xomed NIM Spine (K031510), WR Medical Dual Stim Nerve Stimulator (K063560) and NuVasive NeuroVision JJB System (K051384)

Device Description: The Neural Localization Probe is based on the Baxano Standard Probe (for use with the Ultra Low Profile Rongeur and the Baxano Microblade Shaver) with the modification of circumferential bipolar electrodes. The Neural Localization Probe provides the surgeon additional feedback for localizing the nerve root instead of removing additional bone to improve visualization within the spinal column. A Switch Box directs the stimulus signal so that the nerve can be located on the top, bottom, left or right of the Neural Localization Probe.

Intended Use: The Baxano, Inc. Neural Localization Probe is designed for use with Baxano cutting and biting devices for localization of motor nerves in settings where visualization is compromised.

Substantial Equivalence:

Substantial equivalence of the Neural Localization Probe has been shown to both the existing Baxano Standard Probe, product code HEA, and to surgical nerve stimulators and locators with product code ETN. The Neural Localization Probe has the same indications for use as the Baxano Standard Probe (K080494); it is designed for use with the Baxano Ultra Low Profile Rongeur and the Baxano Microblade Shaver for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column. In addition, it is indicated for use in identification of motor nerves during surgery including spinal nerve roots, the same as surgical nerve stimulators and locators with product code ETN. Any differences between the Neural Localization Probe and Switch Box and the predicates are specific in design and do not raise new questions of safety or effectiveness.

Technological Characteristics:

The Neural Localization Probe is made of stainless steel shaped to enable the surgeon to utilize both direct visualization and tactile feedback in order to evaluate foraminal bone and soft tissue landmarks during placement of Baxano cutting devices. The Switch Box allows energy to be directed from a commercial EMG system to one of four pair of bipolar electrodes so that the surgeon gets feedback as to the relative location of the nerve root to the probe placement.

Non-Clinical Performance Data:

Mechanical performance tests were conducted to verify that the device meets design specifications and intended performance characteristics, based on the application for localization of nerve roots.

The Neural Localization Probe was used in animal studies including blinded studies which established that the nerve root could be identified 100% of the time relative to the Probe positioning. The Neural Localization Probe provided accurate and reproducible real-time feedback about nerve function, even when visualization was impaired.

Conclusions:

Baxano has determined, based on the performance testing and animal studies, that the Neural Localization Probe conforms to the design specifications and is substantially equivalent to the predicate devices for neural stimulation and for use with Baxano devices for accessing and removing soft tissue and bone in the spinal column.

Any statement regarding "substantial equivalence" made in this 510(k) submission and summary only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any *patent proceeding, including patent infringement, litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Baxano, Inc.
% Ms. Trena Depel
Vice President, Regulatory Affairs
2660 Marine Way, Suite B
Mountain View, California 94043

Re: K081742
Trade Name: Baxano Neural Localization Probe
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator.
Regulatory Class: Class II
Product Code: ETN, HAE
Dated: June 18, 2008
Received: June 19, 2008

Dear Ms. Trepel:

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.
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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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K081742**

Device Name: Neural Localization Probe

Indications for Use: The Baxano, Inc. Neural Localization Probe is for use with Baxano cutting and biting devices for localization of motor nerves in settings where visualization is compromised.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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 General, Restorative, and Neurological Devices

510(k) Number K081742