K092729

BAXANO

OCT – 2 2009

510(K) SUMMARY (21 CFR 807.92)

NEURO CHECK DEVICE

510(k) Owner:	Baxano, Inc. 2660 Marine Way, Suite B Mountain View, CA 94043 Tel: 650-937-1400 Fax: 650-937-1410
Contact Person:	Cindy Domecus Tel: (650) 343-4813 E-mail: domecusconsulting@comcast.net
Date Prepared:	September 3, 2009
Trade Name:	Baxano Neuro Check Device
Common Name:	Surgical nerve stimulator/locator
Classification:	Class II, Surgical nerve stimulator/locator (21 CFR 874.1820)
Product Code:	ETN, HAE
Predicate Device Information:	The modified Baxano Neural Localization Probe (now referred to as the Baxano Neuro Check Device) is substantially equivalent to the Baxano Neural Localization Probe, which was determined substantially equivalent on Sept 17, 2008 (K081742).
Device Description:	The modified device allows for addition of monopolar stimulation. A switch directs the stimulus signal so that the nerve can be located relative to the Neuro Check Device. The Neuro Check Device assists in the localization of nerve roots during spinal column surgery where visualization is limited as an alternative to removing additional bone for direct visualization.

Intended Use:	The Baxano, Inc. Neuro Check Device is for use with Baxano cutting and biting devices for localization of motor nerves in settings where visualization is compromised.
Technological Characteristics:	The Neuro Check Device is designed to be placed in the neural foramen to enable the surgeon to direct energy from a commercial EMG system to electrodes on the device enabling feedback regarding relative location of a nerve root to the device. The modification allows for the use of both bipolar and monopolar stimulation. The fundamental scientific technology is unchanged from the predicate.
Non-Clinical Performance Data:	Mechanical and electrical 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 is equivalent to the predicate Neural Localization Probe.
Substantial Equivalence:	The Neuro Check Device is substantially equivalent to the Neural Localization Probe, which was determined substantially equivalent on Sept 17, 2008 (K081742). The Neuro Check Device has the same indications for use and fundamental scientific technology as its predicate. Based upon the indications for use, technological characteristics and performance test results, changes to the Neuro Check Device do not raise new questions of safety or effectiveness.
Conclusions:	Baxano has determined, based on the performance testing and animal studies that the Neuro Check Device conforms to the design specifications and is substantially equivalent to the predicate device.

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

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

Baxano, Inc.
c/o Ms. Patty Hevey
Director of Clinical and Regulatory Affairs
2660 Marine Way
Suite B
Mountain View, CA 94043

OCT - 2 2009

Re: K092729
Trade/Device Name: Baxano Neuro Check Device
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: ETN
Dated: September 3, 2009
Received: September 4, 2009

Dear Ms. Hevey:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092729

Device Name: Neuro Check Device

Indications for Use: The Baxano, Inc. Neuro Check Device is for use with Baxano cutting and biting devices for localization 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)

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

510(k) Number K092729