K100958

JUL 23 2010

BAXANO

510(K) SUMMARY (21 CFR 807.92)

MICROBLADE SHAVER DEVICE AND ACCESSORIES

510(k) Owner:	Baxano, Inc. 655 River Oaks Parkway San Jose, CA 95134 Tel: 408-514-2200 Fax: 408-514-2201
Contact Person:	Edward J. Sinclair Tel: 408-514-2220 E-mail: esinclair@baxano.com
Date Prepared:	April 5, 2010
Trade Name:	MicroBlade Shaver and Accessories
Common Name:	Rongeur, Manual
Classification:	Class II (21 CFR 882.4840)
Product Code:	HAE
Predicate Device Information:	Baxano MicroBlade Shaver and Accessories (K063231) and modified Accessories (K080494).
Device Description:	The modified MicroBlade Shaver device is comprised of a proximal handle, rigid shaft, and flexible cutting platform used for cutting and biting soft tissue and bone. The modified Probe Accessory is comprised of a telescoping proximal handle, cannula, and deployable catheter used to access the decompression site and place the GuideWire. The Distal Handle Accessory is comprised of a handle to accommodate the GuideWire using a wire locking mechanism and wire capture receptacle and allows manual control of the MicroBlade Shaver and Neuro Check devices.

Intended Use:	The Baxano, Inc. MicroBlade Shaver and Accessories are designed for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column.
Technological Characteristics:	The MicroBlade Shaver is designed to be flexible, with a low profile to allow access to compromised neural areas in the spinal column. The accessories include a Probe, Distal Handle and a GuideWire. The fundamental scientific technology is unchanged from the predicate.
Non-Clinical Performance Data:	Bench performance, functional testing and cadaveric analyses were conducted to verify that the device meets design specifications and performance characteristics, based upon the intended use.
Substantial Equivalence:	The modified MicroBlade Shaver Device and Accessories are substantially equivalent to the MicroBlade Shaver and Accessories cleared on April 16, 2007 (K063231) and March 4, 2008 (K080494). The MicroBlade Shaver and Accessories have the same indications for use and fundamental scientific technology as their predicate. Based upon the indications for use, technological characteristics and performance test results, changes to the MicroBlade Shaver and Accessories do not raise new questions of safety or effectiveness.
Conclusions:	Baxano has determined, based on performance testing and cadaver studies that the MicroBlade Shaver device and Accessories conform to the design specifications and are 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

Public Health Service

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

JUL 23 2010

Baxano, Inc.
c/o Mr. Edward J. Sinclair
Vice President, Clinical, Regulatory and Quality Affairs
655 River Oaks Pkwy
San Jose, CA 95134

Re: K100958
Trade/Device Name: MicroBlade Shaver Device and Accessories
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: June 18, 2010
Received: June 23, 2010

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 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

K100958

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100958

Device Name: MicroBlade Shaver Device and Accessories

Indications for Use: The Baxano, Inc. MicroBlade Shaver and Accessories are designed for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column.

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)

Daniel C Clapper

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K100958