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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:	02-22-2012
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 Device and Accessories (K063231, K080494, K100958)
Device Description:	The 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 Probe Accessory is comprised of a telescoping proximal handle, cannula, and deployable catheter used to access the decompression site and place the accessory iO-Flex® Wire. The Distal Handle Accessory is comprised of a handle to accommodate the iO-Flex Wire using a wire locking mechanism and

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wire capture receptacle and allows manual control of the MicroBlade Shaver and Neuro Check® devices.

This 510(k) pre-market notification describes a modification solely to the iO-Flex Wire. The modifications include an additional surface finish process that employs heat treatment and a subsequent chemical etching process applied to the proximal wire section intended to improve the fatigue stress resistance. There were no changes in the wire material and a small change to one nominal dimension.

The modified iO-Flex Wire is manufactured from nickel-titanium ("Nitinol") and is designed to connect to the distal end of the Neuro Check Device and MicroBlade® Shaver device for placement and allows manual control of the MicroBlade Shaver and Neuro Check devices in the neural foramen. The iO-Flex Wire is packaged with the Neuro Check Device and available as a separately packaged accessory device.

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 the iO-Flex Wire. The fundamental scientific technology and operating controls remain unchanged from the predicate iO-Flex Wire design.
Predicate Device Comparison	Modifications were made to the iO-Flex Wire as a result of post market review of iO-Flex Wire complaints. Specific changes and the reason for change are described in the table below:

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	Predicate iO - Flex Wire Specifications	Subject iO - Flex Wire Specifications	Reason for Modification
Dimensional			
Overall iO-Flex Wire Length	26.0"	Same as Predicate	n/a
Barrel Length	0.030"	Same as Predicate	n/a
Proximal Barrel	Ø 0.0350"	Ø 0.0345"	Manufacturing Tolerance
Distal Tip Angulation	11 Degree	Same as Predicate	n/a
Tapered Section	Ø 0.023"	Same as Predicate	n/a
Surface Treatment			
Surface Treatment	Finish to be within 8 microns or better	Heat Treatment and Chemical Etching	Surface Treatment to increase fatigue cycling resistance
Tensile Strength and Fatigue Cycling			
Tensile Strength	≥ 38 lbs.	Same as Predicate	n/a
Fatigue Cycling	12 cycles @ 38 lbs. of tensile load without gross failures	Same as Predicate	n/a
	180 cycles @ 6 lbs. of axial load of simulated decompression	Same as Predicate	n/a
Repeated Connectivity	12 attach/detach cycles without failure	Same as Predicate	n/a

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Non-Clinical Performance Data:	Mechanical bench top comparison testing was conducted on the modified and non-modified iO-Flex Wire designs to verify that the modified iO-Flex Wire meets current design specifications and performance characteristics, based upon the intended use.
Substantial Equivalence:	The MicroBlade Shaver Device and Accessories are substantially equivalent to the MicroBlade Shaver and Accessories (K100958, cleared on July, 23, 2010). The MicroBlade Shaver and Accessories have the same indications for use and fundamental scientific technology as their predicate. The indications for use, technological characteristics and operating controls remain the same. Non-clinical performance test results of the modified iO-Flex Wire do not raise new questions of safety or effectiveness.
Conclusions:	Baxano has determined, based on the same intended use, technological characteristics, operating controls and non-clinical performance testing that the modified iO-Flex Wire 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

Public Health Service

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

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

Re: K113533
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: March 9, 2012
Received: March 12, 2012

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

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Indications for Use

510(k) Number (if known):

Device Name: Baxano 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 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 K113533

Prescription Use X
(Per 21 CFR 801.109)