

K063231

APR 16 2007



## 510(K) SUMMARY (21 CFR 807.92)

### MICROBLADE SHAVER AND ACCESSORIES

510(k) Owner: Baxano, Inc.  
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Mountain View, CA 94043  
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Date Prepared: October, 2006

Trade Name: Microblade Shaver and Accessories

Common Name: Manual rongeur for cutting or biting bone in the skull or spinal column

Classification: Manual rongeur (per 21 CFR section 882.4840)

Predicate Devices: Codman Laminectomy Shaver, Integra Ruggles Instrument, Zeppelin Laminectomy Rongeur Ellman Disc FX System (accessories)

Device Description: The Microblade Shaver and Accessories are used to access the neural foramen and decompress targeted areas. The Microblade Shaver is pulled into the foramen with the Distal Handle and tissue is removed by pulling up on the distal handle to cut the targeted soft tissue and bone. The Accessories include a Probe, Guide, Needle Wire and Distal Handle.

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.

Substantial  
Equivalence:

The Microblade Shaver and Accessories have the same indications for use as the predicates; to access, cut, and bite soft tissue and bone involving the spinal column. In addition, the Accessories have the same intended uses; to access, guide, and probe in neurosurgical applications. Any differences between the Microblade Shaver and Accessories and the predicates are specific in design and do not raise new questions of safety or effectiveness. The device and the predicates are labeled for open decompression procedures.

Technological  
Characteristics:

The Microblade Shaver is made of stainless steel and is flexible, with a low profile, to allow access to compromised neural areas when exposure is otherwise difficult to obtain. These are the same materials and technological characteristics as the predicate devices. The Accessories include a probe, guide and wire substantially equivalent to probes, guides and wires commercially available for discectomy procedures in the lumbar spine.

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 removing bone in compromised neural areas.

The Microblade Shaver and Accessories were used in multiple cadaver studies by physicians skilled in procedures for decompressing neural foramen and lateral recess. Results demonstrated that the Microblade Shaver and Accessories provided comparable tissue removal with no visible damage to neural structures, and an ease of use comparable to the standard of care, when compared to commercially available rongeurs.

Conclusions:

Baxano has determined, based on the performance testing and cadaver studies, that the Microblade Shaver and Accessories conform to the design specifications and are substantially equivalent to the predicate 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.*



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Baxano, Inc.  
% Rockwell & Associates  
Ms. Sharon Rockwell  
VP, Regulatory & Clinical Affairs  
5582 Chalon Road  
Yorba Linda, California 92886

APR 16 2007

Re: K063231  
Trade/Device Name: Microblade Shaver and Accessories  
Regulation Number: 21 CFR 882.4840  
Regulation Name: Manual rongeur  
Regulatory Class: II  
Product Code: HAE  
Dated: March 15, 2007  
Received: March 30, 2007

Dear Ms. Rockwell:

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

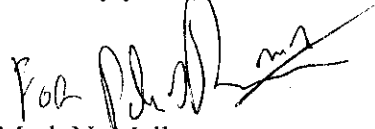
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish extending to the right.

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

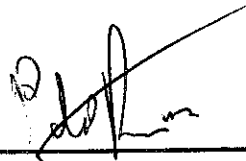
Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): \_\_\_\_\_

Device Name: Microblade Shaver 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.



\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number 16063231

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)