K080494

MAR - 4 2008

SPECIAL 510(K) SUMMARY (21 CFR 807.92)

ULTRA LOW PROFILE RONGEUR

510(k) Owner:	Baxano, Inc. 2660 Marine Way, Suite B Mountain View, CA 94043 Tel: 650-937-1400 Fax: 650-937-1410
Contact Person:	Michael Wallace Tel: 650-937-1400 ext. 408 E-mail: mwallace@baxano.com
Date Prepared:	February, 2008
Trade Name:	Ultra Low Profile (ULP) Rongeur (modified)
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:	Baxano Ultra Low Profile (ULP) Rongeur
Device Description:	The ULP Rongeur and accessory devices are used to access the neural foramen and decompress targeted areas. The Rongeur attaches to a needle wire and is pulled into the foramen with the distal handle also attached to the needle wire. Tissue is removed by pulling up on the distal handle to decompress the impinged nerve root. The accessories include a probe, guide and needle wire, which are used to explore the foramen, and position the needle wire through soft tissue and the skin.
Intended Use:	The Baxano, Inc. Ultra Low Profile Rongeur is designed for accessing, cutting, and biting soft tissue and bone during surgery involving the spinal column.

Substantial Equivalence:	The ULP Rongeur has the same indications for use as the predicate; to access, cut, and bite soft tissue and bone involving the spinal column. The Probe and Guide have been modified to an integrated tool, eliminating the need for the physician to load the Guide for positioning the Needle Wire. Any differences between the modified ULP Rongeur and the predicate do not raise new questions of safety or effectiveness.
Technological Characteristics:	The ULP Rongeur is made of stainless steel and is curved, with a low profile, to allow access to compromised neural areas when exposure is otherwise difficult to obtain. The Probe and Guide have been integrated into one tool, which contains a stiffer Guide for easier manipulation. Two sizes are available to accommodate ipsilateral and contralateral access.
Non-Clinical Performance Data:	Mechanical performance tests were conducted to verify that the modified device meets original design specifications and intended performance characteristics, based on the application for removing bone in compromised neural areas. The ULP Rongeur was used in multiple cadaver studies by physicians skilled in procedures for decompressing neural foramen and lateral recess. Results demonstrated that the ULP Rongeur in combination with the integrated Probe and Guide, provided comparable decompression to the predicate device.
Conclusions:	Baxano has determined, based on the performance testing and cadaver studies, that the ULP Rongeur and accessories conform to the design specifications and are at least as safe and effective as the predicate device for accessing and decompressing 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

Baxano, Inc.
% Ms. Sharon Rockwell
Director, Regulatory Affairs
5582 Chalon Road
Yorba Linda, California 92886

MAR - 4 2008

Re: K080494
Trade/Device Name: Baxano Ultra Low Profile Rongeur
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual rongeur
Regulatory Class: II
Product Code: HAE
Dated: February 20, 2008
Received: February 25, 2008

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 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,

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): K080494

Device Name: Baxano Ultra Low Profile Rongeur

Indications for Use:

The Baxano, Inc. Ultra Low Profile Rongeur is 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)

Mark R. Hyde for mxm

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

510(k) Number K080494