K113073

JUL 27 2012

510(K) SUMMARY (21 CFR 807.92)
iO-TOME DEVICE

510(k) Owner:	Baxano, Inc. 655 River Oaks Parkway San Jose, CA 95134 Tel: 408-514-2200 Fax: 408-514-2201
Contact Person:	Michael Wallace 408.514.2231 mwallace@baxano.com
Date Prepared:	July 27, 2012
Trade Name:	iO-Tome Device
Common Name:	Rongeur, Manual
Classification:	Class II (21 CFR 882.4840)
Product Code:	HAE
Predicate Device Information:	iO-Flex MicroBlade Shaver
Device Description:	The iO-Tome Device is a design modification of the iO-Flex MicroBlade Shaver. It is comprised of a proximal handle, rigid shaft, and flexible cutting platform used for cutting bone for the purpose of removing a facet joint (facetectomy) in the lumbar spinal column. The flexible cutting platform is comprised of two parallel cutting elements that run along a flat flexible metallic substrate. The metallic substrate has two plastic protectors that temporarily cover the parallel cutting elements during introduction of the device into the foramen and protect the underside of the cutting platform during bi-manual reciprocations. After the device is introduced and positioned within the foramen with the use of the iO-Flex System accessories and connected to the iO-Wire and Distal Handle, the user pulls up on the handles thereby exposing the

parallel cutting elements. The user can then proceed with bi-manual reciprocations cutting through the targeted facet joint.

Intended Use:

The iO-Tome Device is used for cutting bone for the purpose of removing a facet joint (facetectomy) of the lumbar spinal column.

Technological Characteristics:

The iO-Tome Device is designed to be a flexible, low profile surgical instrument that allows access to compromised foraminal areas in the lumbar spinal column. The overall design and the fundamental scientific technology is equivalent to the currently cleared predicate MicroBlade Shaver. The FDA cleared iO-Flex technology also includes accessories consisting of the iO-Flex Probe, Neuro Check device, iO-Wire and Distal Handle.

Summary of Non-Clinical Performance Data:

The iO-Tome device was thoroughly tested on the bench to evaluate and verify that it meets its design and performance specifications including biocompatibility, functional and structural integrity.

The bench test plan was developed based on the risk assessment and recommendations outlined in applicable ISO and ASTM standards. Cadaveric and *in vivo* porcine testing confirmed that the subject device meets all design and performance specifications for its intended use. No new/different safety or effectiveness issues were observed during the testing.

Biocompatibility Information:

The iO-Tome is classified as an externally communicating device, in short duration contact (≤24 hr) with tissue and bone. Materials used in the construction of the iO-Tome device that come into patient contact have a long history of use in medical applications and were evaluated and tested in compliance with recognized ISO standard *ISO 10993-1- Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and FDA 21 CFR Part 58 Good Laboratory Practices for Non Clinical Laboratory Study.* The Biocompatibility testing performed for the iO-Tome device included the following:

- Cytotoxicity Study - ISO Elution Method - IX MEM Extract
- ISO Guinea Pig Maximization Sensitization - Test Extract
- ISO Intracutaneous Study in Rabbits – Extract
- ISO Systemic Toxicity Study in Mice – Extract Retest

All of the pre-determined acceptance criteria were met and results passed.

Sterility Information:

The iO-Tome Device is delivered sterile applying a validated accelerated e-beam radiation process to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The following microbiological and irradiation related sterility adoption performance qualification studies were performed in accordance with the following recognized ANSI/AAMI/ISO standards:

Bioburden Recovery Validation Study: *ANSI/AAMI/ISO 11737-1:Sterilization of health care products Microbiological methods - Part 1: Determination of the population of microorganisms on product*

Microbial Bioburden Characterization: *ANSI/AAMI/ISO 11737-1:Sterilization of health care products Microbiological methods - Part 1: Determination of the population of microorganisms on product*

Dose Map Verification Study: *ANSI/AAMI/ISO Standard 11137-2 - Sterilization of health care products – Radiation sterilization – Substantiation of 25 kGy as a sterilization dose –Method VDmax*

The results of above referenced performance testing on representative product samples successfully demonstrated that the MicroBlade Shaver and iO-Tome are considered to be "Equivalent Product" and can be processed with the same validated routine e-beam irradiation process for dosimetric product release.

Pyrogenicity Information:

The iO-Tome device was <u>not</u> tested for bacterial endotoxins and product labeling does not include any information on pyrogenicity.

Stability Information:

Stability testing to determine a minimum shelf life period for product sterility and device integrity was performed according to the following recognized ASTM standards:

ASTM F1980-07: Standard Guide of Accelerated Aging of Sterile Medical Device Packages

ASTM D 4332-01: Conditioning Containers, Packages, or Packaging Components For Testing Standard Practice

ASTM D4169-08: Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM F1980-07: Standard Guide of Accelerated Aging of Sterile Medical Device Packages

ASTM F2096-04: Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)

ASTM F88-09: Standard Test Method for Seal Strength of Flexible Barrier Material

Substantial Equivalence:

The iO-Tome Device is substantially equivalent to the predicate MicroBlade Shaver. The iO-Tome Device has the same indications for use and conforms to the same fundamental scientific technology as the predicate device. Based upon the same indications for use, technological characteristic, design verification and performance testing results, iO-Tome Device does not raise any new or different questions of safety or effectiveness.

Conclusions:

Based on non-clinical performance results including cadaveric and *in vivo* porcine study data, the iO-Tome Device conforms to all design and performance specification and is substantially equivalent to the predicate MicroBlade Shaver device.

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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c/o Michael Wallace
655 River Oaks Parkway
San Jose, California 95134

JUL 27 2012

Re: K113073
Trade/Device Name: i-O Tome Device
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual Rongeur
Regulatory Class: Class II
Product Code: HAE
Dated: June 25, 2012
Received: June 27, 2012

Dear Mr. Wallace:

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,

Deborah Falls

for 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

510(k) Number (if known):

Device Name: iO-Flex® iO-Tome Device

Indications for Use:

The iO-Tome Device is used for cutting bone for the purpose of removing a facet joint (facetectomy) of the spinal column.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Hoffmann

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

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