K102594

BAXANO

JAN 19 2011

510(K) SUMMARY (21 CFR 807.92)
iO-Flex™ Catheter

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:	November 12, 2010
Trade Name:	iO-Flex™ Catheter
Common Name:	Anesthesia Conduction Catheter
Classification:	Class II (21 CFR 868.5120)
Product Code:	BSO
Predicate Devices:	I-Flow Corporation, ON-Q Introducers (K063234) B.Braun, Regional Anesthesia Catheters (K042488) Axiom Medical, Inc., MultiPurpose Wound Drain Catheter (K993592)
Device Description:	The iO-Flex Catheter is comprised of two primary components: (1) Y-Adapter with a rotating hemostasis valve (RHV) and (2) a flexible catheter body. The Y-Adapter consists of two ports: (1) a central guidewire port with rotating hemostasis valve and (2) a side port for connection of a standard syringe for the irrigation, injection and / or aspiration of fluids at the surgical site. The central guidewire port with RHV allows for insertion of the iO-Flex Catheter over the Baxano iO-Flex Wire. The flexible catheter shaft contains external markers for depth adjustment by the clinician.

Intended Use:	The iO-Flex Catheter is for continuous or intermittent preoperative, perioperative or post-operative delivery of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management. The catheter may also be used perioperatively during open spinal procedures to irrigate, aspirate or inject a bolus of fluid or medication. The iO-Flex Catheter is designed for use with the iO-Flex Wire.
Technological Characteristics:	The Baxano iO-Flex Catheter is similar in use and has similar technological characteristics to the I-Flow Corporation ON-Q Introducer, the B. Braun Inc. Regional Anesthesia Catheters and Axiom Medical Inc. MultiPurpose Wound Drain Catheter. All devices incorporate a catheter shaft and a mechanism similar to the iO-Flex Catheter Y-adapter for the irrigation, aspiration or injection of fluids or medications.
Non-Clinical Performance Data:	Bench performance testing was conducted to demonstrate the functional performance of the iO-Flex Catheter and to ensure that the requirements of the product specification were met. iO-Flex Catheters were subjected to double ethylene oxide sterilization, environmental conditioning, and transportation testing prior to undergoing packaging, bench performance and functional testing. Bench performance testing included dimensional, flexibility / kink resistance, leak, guide wire compatibility, ink adhesion, flow rate and tensile strength assessments. Additionally, the packaging and device characteristics were tested after accelerated aging to support shelf-life labeling. The results of the bench testing demonstrated that the iO-Flex Catheter satisfied all of the dimensional and functional performance requirements, which are designed to ensure that the device is safe and effective for its intended use. To verify the biocompatibility of all components and materials for the iO-Flex Catheter, biocompatibility testing was conducted pursuant to FDA's Guidance Document (#G95-1), Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (1995)". Biocompatibility testing was conducted in accordance with the GLP regulations using polar and nonpolar solvents. According to the FDA guidance and ISO standards, the iO-Flex Catheter, is an "external communicating device" in contact with tissue and bone for limited exposure (<24 hour) during spinal procedures. Based on these characteristics, the following biocompatibility tests were conducted: Cytotoxicity, Irritation / Acute Intracutaneous Reactivity, Acute Systemic Toxicity, Sensitization / Maximization and Pyrogenicity. Based on the test results provided, the iO-Flex Catheter has been demonstrated to be biocompatible for its intended use. Design validation testing was conducted to confirm that the iO-Flex Catheter design meets the requirements of the product specification.

Testing was conducted using a cadaver model. The following assessments were performed: Ease of introduction and positioning, guide wire compatibility, irrigation and injection of fluids as well as aspiration. The ability of the catheter to introduce commercially-available hemostatic matrices was validated. The results demonstrate that the iO-Flex Catheter satisfies all of the functional performance requirements, which are designed to ensure that the device is safe and effective for its intended use.

Substantial Equivalence:

The iO-Flex Catheter is substantially equivalent to the I-Flow Corporation ON-Q Introducers (K063224), B. Braun Regional Anesthesia Catheters (K042488), and the Axiom Medical MultiPurpose Wound Drain Catheter (K993592) in terms of its intended use / indications for use, as well as technological characteristics and principles of operation.

The iO-Flex Catheter has the same indications for use and fundamental scientific technology as the predicate devices. Based upon the indications for use, technological characteristics and performance test results, iO-Flex Catheter does not raise any new questions of safety or effectiveness.

Conclusions:

Baxano, Inc. has determined based on bench performance, biocompatibility and cadaver studies that the iO-Flex Catheter conforms to its design specifications and is substantially equivalent to the predicate devices.

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

Mr. Edward J. Sinclair
Vice President, Clinical, Regulatory and Quality affairs
Baxano, Incorporated
655 River Oaks Parkway
San Jose, California 95134

JAN 19 2011

Re: K102594
Trade/Device Name: Baxano iO-Flex Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: December 13, 2010
Received: December 14, 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Baxano iO-Flex Catheter

Indications For Use:
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The iO-Flex Catheter is designed for use with the iO-Flex Wire.

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Device Page 1 of 1

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