K062909
1 of 4

SECTION 5: 510(k) SUMMARY

MAR 0 9 2007

Submitted by:	Baxa Corporation
Contact Person: **Phone:** **Fax:**	Kimberly Zizik, Regulatory Assurance Supervisor (303) 617 2242 (303) 690 4904
Date Prepared:	
Manufacturing Facility:	Baxa Corporation 14445 Grasslands Drive Englewood, CO 80112
Submitted Device:	Trade Name: Repeater Pump II Tube Sets (Baxa Tubing Sets for Pump) Common Name: Set, IV Fluid Transfer
Device Classification:	21 CFR § 880.5440 Intravascular administration set, Product Code LHI (a) *Identification.* An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container. (b) Classification. Class II
Predicate Device:	Trade Name: Repeater™ Pump Tube Sets (Baxa Tubing Sets for Pump) Common Name: Set, IV Fluid Transfer
Predicate Device Classification:	21 CFR § 880.5440 Intravascular administration set Product Code LHI (b) Classification. Class II Manufacturer: Baxa Corporation 510(k) Number: K872743
Product Description:	The Repeater Pump II tube set provides the fluid pathway, pump cavity, valving, and tube set for the Repeater Pump II system. The tube set and pump platform work together to provide sterile transfer and reconstitution of pharmaceutical liquids. The tube set utilizes a plastic piston to mechanically pump required amounts of fluid from 0.2mL to 10mL with each piston stroke. A plastic pump core works in conjunction with the piston to provide appropriate fluid pathways for the draw and discharge strokes.

There are two tube set connections for inlet and outlet fluid pathways. The Repeater Pump II tube set will be available in eight (8) unique configurations to accommodate various source and final container connections.

The Repeater Pump II tube set:

- Provides an integrated pump body/cavity, piston, pump core, and tube set that are used with standard pharmaceutical fluid and drug administration containers
- Utilizes standard connections in different configurations to meet different pumping requirements
- Eliminates the need for frequent calibration and flow factor adjustments normally required with peristaltic pumping
- Designed for pumping life of 200L. Pump automatically alerts users when end of tube set life is met

Intended Use:

The Repeater Pump II tube set is for use with Repeater Pump II device. This device provides piston pump driven fluid transfer that facilitates repeatable drug dosage distribution and reconstitution in hospital pharmacies. The Repeater Pump II tube set provides the fluid pathway and pumping mechanism for the pump system. The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Some sets are sold sterile and others are not based on the requirements for the end use of the set.

Statement of substantial equivalence:
A summary of the essential features between the Repeater Pump Tube sets (Predicate Device) and the Baxa Corporation Repeater Pump II Tube sets (New Device) is contained in below:

Feature	Repeater Pump II Tube Set (Piston Pump New Device)	Repeater Pump Fluid Transfer Tube Set (Peristaltic Pump Predicate Device)
Indication for Use	The Repeater Pump II tube sets are fluid transfer tube sets used in conjunction with the Repeater Pump II pharmacy pump in hospital pharmacies to provide a pathway through which fluid is transferred from one source container into another suitable container.	The Repeater Pump tube set is part of the Repeater Pump™ device. This device provides peristaltic pump driven fluid transfer that facilitates repeatable drug dosage distribution and reconstitution in hospital pharmacies. The Repeater Pump tube set provides the fluid pathway and pumping mechanism for the pump system. The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Some sets are sold sterile and others are not based on the end use of the set.
Intended Use	This product would be used for fluid transfer in hospital pharmacies	This product would be used for fluid transfer in hospital pharmacies
Capacity	10mL per stroke with min/max delivery of .2mL/10mL per stroke and a maximum flow	Inner diameter of pump tube set allows over 14 mL per second to be pumped at the

K060909
3 of 4

	rate of over 21mL per second.	highest speed.
Tubing	Various Durometer Non-DEHP PVC tubing	Various durometer PVC and silicone tubing
Connections	Model #3601 Vented Spike/Male Luer Lock Connectors Fluid Transfer with Vented Spike Model #3603 Male Luer Lock/Male Luer Lock Connectors Fluid Transfer with Luer Lock Connectors Model #3605 Male Luer Lock/Male Luer Lock Connectors Low Prime Volume Fluid Transfer Model #3612 Vented Spikes (2)/Male Luer Lock Bifurcated Tube Set Model #3614 Vented Spike (3)/Male Luer Lock Trifurcated Tube Set Model #3623 SS Weight Inlet/Male Luer Lock Oral Liquid Transfer Model #3620 Male Luer Lock Connector Top Fill Bag Gel Bag Model #3625 Male Luer Lock Connector Top Fill Bag Gel Bag	Model #11 Vented Spike/Male Luer Lock Connectors Fluid Transfer with Vented Spike Model #21 Male Luer Lock/Male Luer Lock Connectors Fluid Transfer with Luer Lock Connectors Model #331 Male Luer Lock/Male Luer Lock Connectors Low Prime Volume Fluid Transfer Model #62 Vented Spikes (2)/Male Luer Lock Bifurcated Tube Set Model #63 Vented Spike (3)/Male Luer Lock Trifurcated Tube Set Model #13 SS Weight Inlet/Male Luer Lock Oral Liquid Transfer Model #26 Male Luer Lock Connector Top Fill Bag Gel Bag Model #46 Male Luer Lock Connector Top Fill Bag Gel Bag
Target Population	Customers for the tube sets are Baxa pharmacy pump users, including hospital and home care pharmacists and pharmacy technicians. These tube sets are used by trained personnel, and do not have direct contact with a patient.	Customers for the tube sets are Baxa pharmacy pump users, including hospital and home care pharmacists and pharmacy technicians. These tube sets are used by trained personnel, and do not have direct contact with a patient.
Anatomical sites	N/A	N/A
Where Used	This product would be used by Pharmacists and Pharmacy technicians both inside and outside of flow hoods	This product would be used by Pharmacists and Pharmacy technicians both inside and outside of flow hoods
Performance	▪ Using a rigid pumping cavity and piston pump methodology, solutions of different viscosities and flow rates can be pumped without any recalibration due to tube set characteristic changes. ▪ Sterilized by Gamma Radiation ▪ Minimum dispensing volume of 0.2mL. ▪ Volume accuracy:	▪ Using different durometer PVC tubing, solutions of different viscosities can be pumped while minimizing dripping from the end of the tube set. Using different silicone tubing diameters, differing volumes can be pumped with repeatable accuracy. ▪ Sterilized by ETO (ethylene oxide) gas. ▪ Minimum dispensing volume of 0.2 mL.

	+/- 0.02ml for .2ml to 2ml pumping +/- 1% for >2ml pumping ▪ High flow tube set allows over 21ml per second to be pumped at highest speed ▪ The pump tube set will perform to specification for up to 200 liters of fluid. Pump automatically alerts users when end of tube set life is met	▪ Volume accuracy: +/- 10% @ 0.2 mL +/- 5% @ 0.5 mL +/- 3% @ 1.0 mL ▪ Inner diameter of pump tube set allows over 14 mL per second to be pumped, highest speed. ▪ The pump tube set will perform to specification for up to 150 Liters of fluid.
Materials	See Section 11, "Device Description" for material information	Fluid contact materials: Sunlite Plastics Vysun 102-85-22 Medical Grade PVC resin Medical Grade silicone tubing
Biocompatibility	Materials will be tested per ISO 10993-1 (2003): Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	Materials have been tested per ISO 10993-1 (2003): Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
Compatibility with the environment and other devices	#3601, #3603, #3605, #3620, #3623 connections are compatible with standard luer-lock connections per ISO 594-1 and -2. #3612, #3614 use a 5mm large bore connector and are compatible only with other 5mm connectors	#11 connections are compatible with standard luer-lock connections per ISO 594-1 and -2.
Sterility	Sterilized using Gamma radiation	Sterilized using Ethylene Oxide (ETO)

From the above table it can be seen that the two types of devices share the same basic features for fluid transfer applications.

Testing: Testing will include:

Biocompatibility testing – ISO 10993-1
Sterilization validation -- ANSI/AAMI/ISO11137
Endotoxin Test - Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices. U.S. Dept. of Health and Human Services and Drug Administration, December 1987.
Human Factors/System Validation
Disposable Design Verification
Microbial Ingress Validation
System Design Verification
Packaging validation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kimberly Zizik
Regulatory Assurance Supervisor
Baxa Corporation
14445 Grasslands Drive
Englewood, Colorado 80112

MAR 0 3 2007

Re: K062909
Trade/Device Name: Repeater Pump II™ Tube Sets
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: February 16, 2007
Received: February 20, 2007

Dear Ms. Zizik:

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.

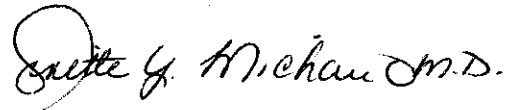
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062909

1 of 1

Indications For Use

510(k) Number: K062909

Device Name: Repeater Pump II™ Tube Sets

Indications for Use: The Repeater Pump II tube set tube sets are fluid transfer tube sets used in conjunction with the Repeater Pump II pharmacy pump in hospital and compounding pharmacies to provide a pathway through which fluid is transferred from one source container into another suitable container.

Prescription Use ___X___ (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)

K062909