K022523

AUG 12 2002

510(k) Summary

Submitted by: Baxa Corporation
13760 E. Arapahoe Road
Englewood, CO 80112

Contact Person: Karl Steineck
Phone: 303-617-2181
Fax: 303-690-4804

Date Prepared: July 26, 2001

Manufacturing Facility: Baxa Corporation
13760 E. Arapahoe Road
Englewood, CO 80112

Submitted Device: Trade Name: Rapid-Fill™ Tubeset(s)

Common Name: Administration Set

Device Classification: Class II

21 CFR § 880.5440 Intarvascular administration set

(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 (performance standards)

Predicate Device: Exacta-Mix™ 2400 Compounding System Administration Set
510(k): K002705, Cleared March 28, 2001
Baxa Corporation
Englewood, CO

K022523

Product Description: The Rapid-Fill Tubeset, is a tubeset used in conjunction with the Rapid-Fill pharmacy pump to fill multiple syringes.

Intended Use: The Rapid-Fill Tubeset, is a fluid transfer device used in the pharmacy to provide the fluid path for transfering large source container ingredients into a smaller containers.

Statement of substantial equivalence-

The Rapid-Fill Tubeset is very similar to the Exacta-Mix 2400 Compounding System Administration set in the following areas; intended use, operation, and function. The Rapid-Fill Tubeset and the predicate device are both used to transfer large source into smaller containers.

A summary of the essential features between the Exacta-Mix 2400 Compounding System Administration set (predicate device) and the Rapid-Fill Tubeset is contained in Table 1

Table 1

Comparison between the Exacta-Mix™ 2400 Compounding System Administration Set and the new device, Rapid-Fill tubeset.

Feature	Exacta-Mix Administration Set (Predicate Device)	Rapid-Fill™ Tubeset
Intended use	used to transfer multiple large container ingredients into one final solution	Used to transfer one large container ingredient to multiple small containers.
Inlet Spike	Vented and non-Vented source container spike	Vented and non-Vented source container spike
Tubing	Non- DEHP Polyvinyl Chloride (PVC)	Non- DEHP Polyvinyl Chloride (PVC)
Sterile Fluid Path	Radiation Sterilized	Radiation Sterilized

From Table 1 it can be seen that the two types of devices share the same basic features for fluid transfer.

Testing:

Testing will include: Biocompatibility testing – ISO 10993-1
Packaging validation
Sterilization validation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

Mr. Karl Steinbeck
Baxa Corporation
13760 East Arapahoe Road
Englewood, California 80112

Re: K022523
Trade/Device Name: Rapid-Fill Tubeset, Model 90005
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: July 19, 2002
Received: July 30, 2002

Dear Mr. Steinbeck:

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.

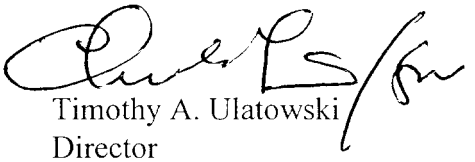
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION I: PRE-MARKET SUBMISSION (CONTINUED)

Indications for Use Statement (New and Predicate Device)

New Device

Applicant: **Baxa Corporation**
510(k) Number (if known) _____

New Device Name: **Rapid-Fill™ Tubeset**

Indications For Use: The Rapid-Fill Tubeset, manufactured by Baxa Corporation, is a fluid transfer device used in the pharmacy to provide the fluid path for transferring large source container ingredients into a smaller containers.

Patricia Cucuzza
(Division Sign-Off)
Division of Anesthesiology, Gener
Infection Control, Dental Devices

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