

OCT 6 1998

SAFETY AND EFFECTIVENESS SUMMARY
Baxa MicroFuse™ Dual Rate Infuser

Name and address of Device Manufacturer submitting 510(k) Notification:

BAXA CORPORATION
13760 E. Arapahoe Road
Englewood, Colorado 80112

Regulatory Correspondent of Device Manufacturer:

Patrick Hynes
Baxa Corporation
13760 E. Arapahoe Road
Englewood, Colorado 80112
Phone: (303)690-4204
FAX: (303)690-4802

Date Summary was prepared:

July 31, 1998

Name of the device:

MicroFuse™ Dual Rate Infuser

Classification:

Pump, infusion, Class II per 880.5725

Indications for Use:

The device is intended to be used for the intermittent administration of I.V. medication.

Description of the device:

The Baxa Corporation MicroFuse Dual Rate Infuser, is a battery powered, portable device that automates the injection of the contents of a syringe into a patient. Each MicroFuse has two pre-determined rates that are be preset at the manufacturing facility. These preset rates can not be modified by the user or patient. The MicroFuse is used with a sterile administration set for injecting the medication into a patient. It depresses the plunger of the syringe at a controlled, pre-

determined rate, delivering the dose in the syringe over an extended period of time. The MicroFuse is offered in a standard dual rate model. Some custom dual rate models with the only difference being the pre-determined infusion rates are also offered.

The MicroFuse System consists of the MicroFuse Dual Rate Infuser and a syringe and administration set. Both syringe and administration sets are sterile and disposable. Since only the accessory syringes and administration sets are in the fluid path, the MicroFuse has **no patient contact materials**. This also means the device is not provided sterile, nor is it sterilized in the field. The accessories have been previously cleared with the predicate device in K933506.

Substantial Equivalence:

The Baxa MicroFuse is substantially equivalent to:

Syringe Infuser
510(k) K933506, Cleared February 25, 1994
Baxa Corporation
Englewood, CO

Safety and Efficacy:

The MicroFuse™ has been tested to all applicable requirements of ANSI/AAMI ID26-1992, Standard for Infusion Devices. The MicroFuse met all the applicable requirements of the Standard.



OCT 6 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Baxa Corporation
C/O Mr. William E. McKay
President
Regulatory Consultants to the Medical Device Industry (RCMDI)
9712 S. Altamont Drive
Sandy, Utah 84092

Re: K983321
Trade Name: MicroFuse™ Dual Rate Infuser
Regulatory Class: II
Product Code: RDN
Dated: September 22, 1998
Received: September 22, 1998

Dear Mr. McKay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

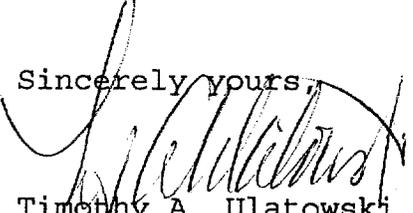
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not yet assigned

Device Name: MicroFuse™ Dual Rate Infuser

Indications For Use:

The Baxa Corporation MicroFuse™ Dual Rate Infuser is intended to be used for the intermittent administration of I.V. medication.

This intended use is identical to the intended use for the predicate device as cleared for marketing in K933506, Baxa Dual Rate Infuser, Cleared February 25, 1994.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Patricia Cruce (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 983321