

**510(k) SUMMARY**

**Vial-Mate Reconstitution Device**

**Submitted by:**

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I.V. Systems Division  
Rte. 120 and Wilson Road  
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OCT 24 1997

**Date Prepared:**

September 24, 1997

**Proposed Device:**

Vial-Mate Reconstitution Device

**Predicate Devices:**

ReconPlus™ Reconstitution Device

**Proposed Device Description:**

The Vial-Mate Reconstitution Device is an accessory intended for use by the pharmacist or health practitioner in the reconstitution and transfer of drugs into Baxter solution containers. This product is similar to the currently marketed Baxter ReConPlus™ Reconstitution Device, cleared under K910793 on March 21, 1991. Like the ReConPlus™ Reconstitution Device, it provides a means of connecting a standard 20 mm single dose drug vial to an I.V. solution container without reconstituting and mixing the vial contents with the diluent until immediately before administration of the drug to the patient.

There is one solution contact material in the proposed Vial-Mate Reconstitution Device which is new to Baxter. It is an elastomeric material which is used in the septum of the device. The other solution materials used in the proposed device were previously tested and used in other Baxter devices for similar IV solution administration applications.

**Statement of Intended Use:**

The proposed Vial-Mate Reconstitution Device has the same intended use as previously cleared devices of its type. The Vial-Mate Reconstitution Device is intended to provide the pharmacist or health practitioner a means of connecting a standard 20 mm single dose drug vial to an I.V. solution container without reconstituting and mixing the vial contents with the diluent until immediately before administration of the drug to the patient.

### **Summary of Technological Characteristics of New Device to Predicate Devices**

The existing ReConPlus™ Reconstitution Device uses a one step motion for reconstitution where a frangible plastic cannula (breakaway seal) is broken. The proposed Vial-Mate Reconstitution Device uses a two-step rotating action for drug reconstitution. In addition, while the ReConPlus™ device penetrates the drug vial stopper when attached, the Vial-Mate device can be pre-attached without penetration into the stopper until ready for activation and use through the two-step rotating action.

### **Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature**

The biological and chemical reactivity of the new solution contact material have been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The material was found to be acceptable for its intended use.

Data regarding the functional performance of the proposed Vial-Mate have been generated and submitted. The data indicate that the proposed reconstitution device meets or exceeds all functional requirements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

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OCT 24 1997

Re: K973654  
Trade Name: Vial-Mate Reconstitution Device (2B8071)  
Regulatory Class: II  
Product Code: LHI  
Dated: September 24, 1997  
Received: September 25, 1997

Dear Dr. Itani:

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 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.

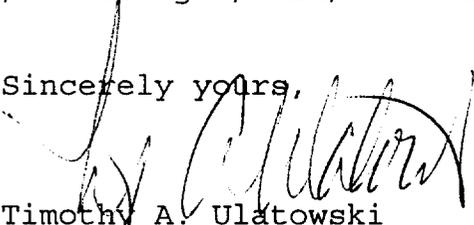
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4618. 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" (21 CFR 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/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

**Indication for Use**

**510(k) Number:** Not Available

**Device Name:** Vial-Mate Reconstitution Device

**Indication for Use:**

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*Patricia Ciccarelli*  
**(Division Sign-Off)**  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K973654

Prescription Use   
(Per 21 CFR 801.109)