

DEC 13 2002

K 023491

## SUMMARY OF SAFETY AND EFFECTIVENESS

September 20, 2002

**Trade Name:** AutoMed 3300 and AutoMed 3400 infusion pumps

**Common Name:** Infusion Pump

**Classification Name:** Pump, Infusion,

**Classification Panel:** General Hospital and Personal Use Device

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq.  
Managing Director

HELP Technologies  
24312 Armada Dr.  
Dana Point, CA 92629  
Telephone: 949.235.0545  
Fax: 949.240.3460

### 1.0 DEVICE DESCRIPTIONS

The AutoMed Systems presented in this product notification include the AM 3300 and AM 3400 rotary peristaltic pumps and associated dedicated administration sets (AM 320, AM 330 and AM 340) and accessories. The systems are suitable for use as ambulatory devices and that are intended for use in the hospital, home environment or alternative care sites.

### 2.0 INTENDED USE

For general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, inter-arterial and epidural and into the intra-operative (soft tissue / body cavity) site.

General infusion use includes continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative surgery.

### 3.0 PREDICATE PRODUCTS

The AutoMed 330 and 3400 are substantially similar to the following devices: McKinley WalkMed® 300, 350, PCA and IC; Sorenson Medical, Inc, MicroJect® Model 30 pump, Model 200 Pump, Model PCA Pump, Model PCEA Pump; Stryker Instruments Pain Pump II; and the I-Flow PainBuster Infusion Kit.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

DEC 13 2002

Mr. Robert J. Bard  
Managing Director  
Help Technologies  
24312 Armada Drive  
Dana Point, California 92629

Re: K023491

Trade/Device Name: AutoMed 3300 and 3400 Pump systems  
Regulation Number: 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: FRN and MEA  
Dated: September 20, 2002  
Received: October 17, 2002

Dear Mr. Bard:

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.

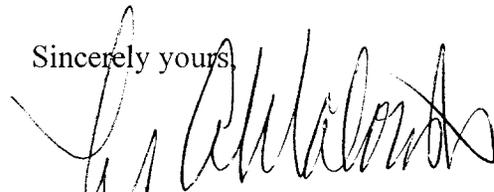
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 (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

510(k) Number (if known): K 023491

Device Name: AutoMed 3300 and 3400 pump systems

**Indications for Use:**

The *AutoMed* 3300 and 3400 ambulatory infusion pumps and dedicated administration sets and accessories are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, inter-arterial and epidural, and into intra-operative (soft tissue / body cavity) sites. The *AutoMed* systems are also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative surgery.



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

510(k) Number: K023491

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED 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

(Optional Format 1-2-9)