K030136

VIII. PREMARKET NOTIFICATION 510K SUMMARY

APR 07 2003

SUBMITTER INFORMATION

A. Company Name: Drip Alert, Inc.

B. Company Address: 13882 N. Kendall Dr.
Miami, Florida 92121

C. Company Phone: 305-385-8000
Company Fax: 305-388-3965

D. Contact Person: Dr. Barry Goldberg

E. Date Summary Prepared: January 9, 2003

DEVICE IDENTIFICATION

A. Generic Device Name: I.V. drip monitor

B. Trade/Proprietary Name: Drip Alert

C. Classification: Monitor, Electric for Gravity Flow Infusion Systems
21 CFR 880.2420, Class II, General Hospital
Product Code FLN

INDICATION FOR USE

The Drip Alert device is a passive device that measures time between intravenous drops and sounds an alarm when the time between drops falls outside an acceptable range due to air in the line, occlusion, low or empty fluid in the solution bag, high or low flow rate, and low battery.

SUBSTANTIAL EQUIVALENCE

The Drip Alert intravenous drip monitor and alarm is of a comparable type and is substantially equivalent to the predicate devices, MT Alert Infusion Monitor made by Seirra BioSearch, Inc. K022248 and the drop counter and alarm profiles which are components of the Gemini Infusion System made by Alaris Medical Systems, Inc. K012383 and the Sigma programmable infusion pump with optional flow sensor manufactured by Sigma K950766. The Drip Alert device does not have a pump or clamping mechanism.

SUBSTANTIAL EQUIVALENCE CHART

Feature	Drip Alert™	MT Alert™	Gemini® Infusion Pump	Sigma with optional flow sensor
Passive device, no fluid control	Yes	Yes	No	No
Used for monitoring the rate of infusion	Yes	No	Yes	Yes
Accommodates most typical infusion administration sets	Yes	Yes	Yes	Yes
Sounds and alarm when infusion is low or complete	Yes	Yes	Yes	Yes
Uses a processor to perform calculations and measurements	Yes	Yes	Yes	Yes
Has a flow meter	Yes	No	Yes	Yes
Sounds an alarm when there is a deviation in flow rate	Yes	No	Yes	Yes
Sounds a low battery alarm	Yes	Yes	Yes	Yes
Power Source	2-AAA batteries, typical 30 day life	2-AA batteries, typical 180 day life	Sealed lead battery 5 hours on fully charged battery or external source	Rechargeable battery 4 hour to low battery alarm
Class II Device	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 7 2003

Drip Alert, Incorporated
C/O Ms. Polly D. Heseman
Gunster, Yoakley & Stewart P.A.
500 E. Broward Boulevard, Suite 1400
Ft. Lauderdale, Florida 33394

Re: K030136
Trade/Device Name: Drip Alert
Regulation Number: 880.2420
Regulation Name: Electronic Monitor for Gravity Flow Infusion Systems
Regulatory Class: II
Product Code: FLN
Dated: January 10, 2003
Received: January 14, 2003

Dear Ms. Heseman:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. STATEMENT OF INDICATION OF USE

The Drip Alert device is intended to be used as a supplementary monitor with a standard IV administration set such that an alarm sounds when the drip rate in the drip chamber of the administration set falls outside a preselected range of acceptable drip rate deviation. The deviation in the drip rate may be due to air in the IV line, occlusion, excessive movement by the patient or displacement of the IV catheter.

Patricia Cicenia

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

510(k) Number: K030136