



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

October 13, 2015

Shift Labs  
C/O Mr. Steven Chernoff  
Vice President  
Drug & Device Development Co.  
P.O. Box 3515  
Seattle, Washington 98073

Re: K150687

Trade/Device Name: DripAssist  
Regulation Number: 21 CFR 880.2420  
Regulation Name: Electronic Monitor for Gravity Flow Infusion Systems  
Regulatory Class: II  
Product Code: FLN  
Dated: September 8, 2015  
Received: September 11, 2015

Dear Mr. Steven Chernoff:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. In the background, there is a faint, large watermark of the letters "FDA".

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150687

Device Name

DripAssist

Indications for Use (Describe)

The DripAssist is a device intended to be used as a supplementary monitor that measures the flow of fluid through the drip chamber of a standard IV administration set. Sensors measure the flow rate and calculations are performed to convert the drip rate to ml/hr measurement and total volume. An alarm is available to alert the user if the drip rate deviates from the infusion rate setting controlled through the IV administration set.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Section 5. 510(k) Summary (21 CFR 807.92)****Date prepared:** October 8, 2015**Submitter:**

Shift Labs  
1752 NW Market St. #211  
Seattle, WA 98107

**Contact Person:**

Beth Kolko  
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Email: [beth@shiftlabs.com](mailto:beth@shiftlabs.com)

**Proprietary name:**

DripAssist

**Common name:**

IV flow rate monitor

**Classified name:**

Electronic monitor for gravity flow infusion systems  
CFR 880.2420 Product code: FLN Regulatory Class: II

**Predicate Device:** Drip Alert K030136**Intended use:**

The DripAssist is a device intended to be used as a supplementary monitor that measures the flow of fluid through the drip chamber of a standard IV administration set. Sensors measure the flow rate and calculations are performed to convert the drip rate to mL/hr measurement and total volume. An alarm is available to alert the user if the drip rate deviates from the infusion rate setting controlled through the IV administration set.

**Substantial equivalence:**

The DripAssist is substantially equivalent to the Drip Alert (K030136).

**Description of device:**

The DripAssist device is intended to be used as a supplementary monitoring system for monitoring the flow rate of intravenous fluids. The DripAssist is a passive device. It does not control the flow rate of fluids passing through a drip chamber. The device operates by monitoring the drops through the drip chamber of a standard IV administration set. By tracking the intervals between drops, the device calculates the flow rate through the chamber and displays the flow rate on an LCD screen.

The device operates by tracking drops using an infrared emitter and detector positioned on opposite sides of a well wherein the drip chamber is situated.

There is an alarm functionality that can be activated once a desired flow rate, or "set point," is reached. The alarm, when activated, will sound when the flow rate deviates from a fixed percentage from the "set point."

The device can be used with drip sets of 10, 15, 20, and 60 gtt/mL. The device is powered by one AA battery. The device can display the flow rate in drops per minute or mL per hour. The unit of measurement being displayed can be changed while the device operates. The device can also display the total volume that has dispensed through the drip chamber. The device is designed to be used with drip rates slow enough to be calculated by the human eye; a steady stream of fluid is outside the operating parameters.

**Summary of technological characteristics and indication for use compared to predicate device:**

Both the DripAssist and the Drip Alert are intended to be used with standard size gravity feed IV administration sets as a monitor to inform the user of the rate of flow, which is controlled by the IV administration set. Neither device controls the flow rate, but uses sensors and microprocessors to measure and calculate the flow rate. Both devices include audio alarms when the flow rate deviates from a pre-set range. Both devices are powered by disposable batteries.

**Indication for Use**

<b>Drip Assist</b>	<b>Drip Alert</b>
The DripAssist is a device intended to be used as a supplementary monitor that measures the flow of fluid through the drip chamber of a standard IV administration set. Sensors measure the flow rate and calculations are performed to convert the drip rate to mL/hr measurement and total volume. An alarm is available to alert the user if the drip rate deviates from the infusion rate setting controlled through the IV administration set.	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.

**Technological characteristics**

	<b>DripAssist</b>	<b>Drip Alert</b>
Passive monitor; does not control flow rate	Yes	Yes
Device status information to user	LCD screen includes status information and audio alarm signals	Unique audio signals for four different conditions: power on; calculating drip rate; drip rate deviation; low battery
Microprocessor and algorithms used for measurements and calculations	Yes	Yes

Drip rate setting method	Three drops; monitored by user to determine accuracy before activating setting	Nine drops used by microprocessor to calculate drip rate
Used with standard IV administration sets	Yes (10, 15, 20, and 60 gtt/mL)	Yes
Infrared sensor detection of flow rate	One emitter, one receiver	One emitter, two receivers
Audio alarm when flow rate is outside preset range	Yes	Yes
Drip rate range	0.15 – 30 seconds	0.5 - 12 seconds
Range variability to trigger alarm	+/- 13% (not including 5% accuracy variability)	Two thresholds set by user: +/- 12.5% or +/- 18.75%
Materials	Plastic Housing: ABS Blue Parts (Cam, bumpers): Silicone Front overlays: PET	Not publically available
Power source	1 AA battery	2 AAA batteries

**Non-Clinical Testing:**

The following performance tests were completed on the subject device for determination of substantial equivalence to the predicate device.

- Drip Rate Accuracy Test
- Alarm Accuracy Test
- IEC 60601-1-2:2007 Ed: 3 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Test
- Design Verification and Validation test

**Conclusion:**

The conclusions drawn from the performance tests demonstrate that the subject device performs as well as the legally marketed device and the DripAssist is substantially equivalent to the Drip Alert.