May 25, 2018

Shift Labs, Inc.
Camelia Kouki
Director, QA/RA
1600 Dexter Ave N, Suite A
Seattle, Washington 98109

Re: K172242
Trade/Device Name: DripAssist Plus
Regulation Number: 21 CFR 880.2420
Regulation Name: Electronic Monitor for Gravity Flow Infusion Systems
Regulatory Class: Class II
Product Code: FLN
Dated: April 21, 2018
Received: April 25, 2018

Dear Ms. Camelia Kouki:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172242

Device Name
DripAssist Plus

Indications for Use *(Describe)*
The DripAssist Plus is a device intended to be used with gravity infusions as a supplementary monitor that measures the flow of fluid through a compatible drip chamber. The device is intended to be used with single-use intravascular administration sets uniquely identified as "compatible with DripAssist Plus." 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 set 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.

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Section 5. 510(k) Summary (21 CFR 807.92(c))

Date prepared: April 16, 2018

Submitter:
Shift Labs Inc.
9200 Holman Road NW Seattle, WA 98117

Contact Person:
Camelia Kouki
Ph: 206-369-1216
Email: camelia@shiftlabs.com

Proprietary name:
DripAssist Plus

Common name:
IV flow rate monitor

Classified name:
Electronic monitor for gravity flow infusion systems
CFR 880.2420 Product code: FLN

Classification:
Class II Medical Device

Predicate Device: DripAssist K150687

Indications for use
The DripAssist Plus is a device intended to be used with gravity infusions as a supplementary monitor that measures the flow of fluid through a compatible drip chamber. The device is intended to be used with single-use intravascular administration sets uniquely identified as "compatible with DripAssist Plus." 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 set infusion rate setting controlled through the IV administration set.

Substantial equivalence
The DripAssist Plus is substantially equivalent to the DripAssist (K150687).

Description of Device

The DripAssist Plus device is intended to be used as a supplementary monitoring system for monitoring the flow rate of intravenous fluids. DripAssist Plus 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 compatible single-use intravascular administration set that is inserted into a mechanical attachment mechanism on the DripAssist Plus. 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 a fixed percentage from the "set point."

The device can be used with compatible drip sets of 10, 15, 20, or 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 compared to predicate devices

Both the DripAssist Plus and the DripAssist have the same technological characteristics and both are intended to be used 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 each uses sensors and microprocessors to measure and calculate the flow rate. Both devices include audio alarms for when the flow rate deviates from a pre-set range. Both devices are powered by disposable batteries. Both devices have the same internal electrical layout and components except for (1) a swap to a microprocessor chip with identical architecture but more memory, and (2) the removal of a capacitor. Both devices attach to the outside of a drip chamber on a drip set; the predicate device uses a cam and bumpers to attach whereas the subject device uses a snap-in attachment.

	DripAssist Plus	DripAssist (K150687)	Change Analysis
Device class	Class II	Class II	No Change
Indications for Use	The DripAssist Plus is a device intended to be **used with gravity infusions** as a supplementary monitor that measures the flow of fluid through a compatible drip chamber. **The device is intended to be used with single- use intravascular administration sets uniquely identified as "compatible with DripAssist Plus."** 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 set infusion rate setting controlled through the IV administration set.	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 difference in indication for use is that the predicate states: "measures the flow of fluid through the drip chamber of a standard IV administration set." For the DripAssist Plus, the indication for use states: "measures the flow of fluid through a compatible drip chamber. The device is intended to be used with single-use intravascular administration sets uniquely identified as "compatible with DripAssist Plus." DripAssist Plus is a mechanical variant of the DripAssist infusion rate monitor. The mechanical design has been changed to provide a solution for use solely with compatible administration sets, as opposed to all standard infusion sets.
Product Configuration	Single SKU for all markets - One device, user manual, shipping materials	Single SKU for all markets - One device, user manual, shipping materials	No Change
Components	One-piece device plus supplied AA battery	One-piece device plus supplied AA battery	No Change

Performance Testing	DripAssist Plus Chamber Wear Test Plan, DripAssist Plus Chamber Wear Test Results, DripAssist Plus Insertion Force for Collar Attachment Test Results, DripAssist Plus Insertion Force for Collar Attachment Test Plan,DripAssist AVR - Firmware DVT Test Report FW2.5.5.37, DripAssist Genoa System DVT Test Plan, DripAssist Genoa System DvT Report, Genoa Cleaning Chemical Tests, Genoa Drop Test Plans and Results	Device Verification Testing , DVT Test Report, Infusion Time Study, DripAssist Babylon - EMC Test Report, DripAssist Babylon - System DVT Plan, DripAssist Babylon - System DVT Report	Additional testing for the subject device has been added. These tests can be grouped into three categories: (1) performance testing for device wear and attachment , (2) performance testing for device firmware, (3) performance testing for device durability.

Performance/Technical Specifications			
	DripAssist Plus	**DripAssist (K150687)**	**Change Analysis**
Infrared sensor detection of flow rate	One emitter, one receiver	One emitter, one receiver	No change
Audio alarm when flow rate is outside preset range	Yes	Yes	No change
Drip rate range	4-400 drops/min	4-400 drops/min	No change
Drip rate measurement accuracy	1%	1%	No change
Rate change to trigger alarm	Set Rate +/- 13%	Set Rate +/- 13%	No change
Power source	1 AA battery	1 AA battery	No change
Operation environment	Room temperature. 65-85 degrees Fahrenheit at 30-70% humidity, non- condensing, at altitude less than 3000 meters.	Room temperature. 65-85 degrees Fahrenheit at 30-70% humidity, non-condensing, at altitude less than 3000 meters.	No change
Sterility	N/A	N/A	No change
Dimensional Characteristics	133.4 x 67.6 x 30.5 mm	128 x 62 x 30 mm	Subject device is slightly larger.

Materials	ABS, PET	ABS, PET, Silicone	The subject device materials do not contain anything different than the materials on the predicate device. The only difference is that silicone components (cam and bumpers) on the predicate device have been removed from the subject device
Major Components	LCD Display, four touch buttons, Battery cover, audio alarm, administration set attachment point	LCD Display, four touch buttons, Battery cover, audio alarm, cam securing mechanism	The differences between the subject device and the predicate device are the predicate device uses a cam securing mechanism to attach to drip sets. The subject device has an integrated "administration set attachment point." In other words, the silicone cam used to "grip" most standard tubing sets in the predicate device has been removed. Compatible tubing sets now use a friction fit into a slot on the top of the device.
Electrical Safety	EMC Test Report	EMC Test Report	Circuit design is identical. MCU is same, but with more memory. Capacitor has been depopulated, change is mechanical not electrical. No change in shielding. No changes are made that affect emissions.

The initial DripAssist was bench tested to verify drip rate flow measurements are accurate and the alarm functions as intended. DripAssist Plus repeated all those tests; results were acceptable for all testing.

Although most aspects of the DripAssist Plus remain the same as the predicate (DripAssist), for the aspects of the subject device that are new or modified, additional testing was done. Testing needs were determined based on the device specifications to fulfill verification and validation of the product, as well as potential risks identified during the risk assessment process.

Summary of non-clinical testing

Below outlines the non-clinical testing conducted. These non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met. These test results demonstrate equivalence to the predicate device.

Areas Tested:

- Mechanical durability of the DripAssist Plus attachment mechanism
- Mechanical insertion and removal force testing for adherence to specifications
- Device firmware verification/accuracy testing
- Device cleaning
- Mechanical durability (drop testing)
- Operational temperature testing
  Testing for general requirements for basic safety and essential performance, IEC 60601-1:2012
- Alarm testing
- EMC/EMI testing for medical device compliance
  EMC Test, IEC 60601-1-2:2007
- Tracing design requirements to verification methods to verify performance standards (V&V)

Conclusion

Based on the review of intended use, functional application, and design, the DripAssist Plus is substantially equivalent to the predicate device K150687.