### **Section 10 – Executive Summary**

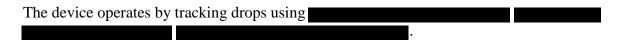
The Shift Labs DripAssist is an IV administration set flow rate monitor.

### Indications for 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.

## **Device description**

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.



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.

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### Comparison to predicate

Shift Labs believes that its DripAssist flow monitor for gravity feed IV infusion administration sets is substantially equivalent to the Drip Alert device (K030136). The two devices have similar or the same intended use statements and technological characteristics.

### **Intended use**

DripAssist	<b>Drip Alert (K030136)</b>
The DripAssist is a device intended to be	The Drip Alert device is intended to be used
used as a supplementary monitor that	as a supplementary monitor with a standard
measures the flow of fluid through the drip	IV administration set such that an alarm
chamber of a standard IV administration	sounds when the drip rate in the drip
set. Sensors measure the flow rate and	chamber of the administration set falls
calculations are performed to convert the	outside a preselected range of acceptable drip
drip rate to mL/hr measurement and total	rate deviation. The deviation in the drip rate
volume. An alarm is available to alert the	may be due to air in the IV line, occlusion,
user if the drip rate deviates from the	excessive movement by the patient or
infusion rate setting controlled through the	displacement of the IV catheter.
IV administration set.	

**Technological characteristics** 

3	DripAssist	Drip Alert
Passive monitor; does not control	Yes	Yes
flow rate		
Microprocessor used for	Yes	Yes
measurements and calculations		
Used with standard IV	Yes	Yes
administration sets		
Sensor detection of flow rate	Yes	Yes
Audio alarm when flow rate is	Yes	Yes
outside preset range		
Power source	1 AA battery	2 AAA batteries

## Discussion of substantial equivalence

Both the DripAssist and the Drip Alert are intended to be used with standard 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.

Testing	
The DripAssist was bench tested	
The accuracy testing	

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An alarm verification test was conducted to verify