

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.

The device operates by tracking drops using [REDACTED] [REDACTED]

[REDACTED] [REDACTED].

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. [REDACTED]

[REDACTED]
[REDACTED] s.

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	Drip Alert (K030136)
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 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.

Technological characteristics

	DripAssist	Drip Alert
Passive monitor; does not control flow rate	Yes	Yes
Microprocessor used for measurements and calculations	Yes	Yes
Used with standard IV administration sets	Yes	Yes
Sensor detection of flow rate	Yes	Yes
Audio alarm when flow rate is outside preset range	Yes	Yes
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 [REDACTED]

[REDACTED].

The accuracy testing [REDACTED]

[REDACTED]. [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

An alarm verification test was conducted to verify [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]