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

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Proprietary name:
DripAssist

Common name:
IV flow rate monitor

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

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.

[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]

Summary of technological characteristics compared to predicate devices

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

[redacted]