

Indications for Use

510(k) Number (if known)

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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