Table 5-2. Predicate devices SMARTeZ Pump is substantial equivalent (SE*) with

Predicate Devices				
510(k) No.	K052117 (Primary)	K071222	K081905	K991513
510(k) Submitter	I-Flow Corporation	Baxter Healthcare Corporation	Westmed. Inc. (B. Braun Medical Inc.)	I-Flow Corporation
Trade Name	I-Flow Elastomeric Pump (Homepump/ Easypump)	Infusor SV and LV Elastomeric Infusion Devices	AccuFlo, AccuFlux	Homepump C- Series

(*SE: Substantial Equivalence)

5.4 Device Description

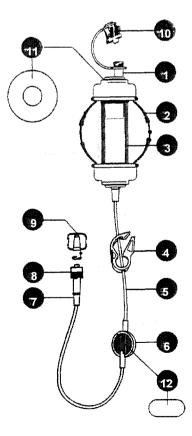
The SMARTeZ Pump, is a single-use disposable, non-electric infusion pump that consists of an elastomeric fluid reservoir as energy source with an integrated administration line (see Figure 5-1). The constriction of elastomeric fluid reservoir drives the medication through the tubing and eventually through a flow restrictor out into the patient connection. Drug products should be stored in their approved containers and closures.

Figure 5-1. Diagram of the SMARTeZ Pump

SMART oz ™ Pump

Portable single use elastomeric infusion pump

- 1. Fill port
- 2. Outer soft cover
- 3. Multi-lavered elastomeric membrane
- 4. ON-OFF clamp
- PVC administration tubing not made from Phthalate (DEHP)
- 6. Air and particulate eliminating filter
- 7. Flow restrictor
- 8. Patient connector
- 9. Patient end cap
- 10. Fill port cap (tethered)
- 11. Labelling Fill volume & infusion time
- 12. Labelling Flow rate



Section §5: 510(k) Summary (K151650)