

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

Predicate Devices				
<b>510(k) No.</b>	K052117 (Primary)	K071222	K081905	K991513
<b>510(k) Submitter</b>	I-Flow Corporation	Baxter Healthcare Corporation	Westmed. Inc. (B. Braun Medical Inc.)	I-Flow Corporation
<b>Trade Name</b>	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**

**SMARTeZ™ Pump**

Portable single use elastomeric infusion pump

1. Fill port
2. Outer soft cover
3. Multi-layered elastomeric membrane
4. ON-OFF clamp
5. 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

