

g. Summary of Safety and Effectiveness

Collection of patient's shed blood for Autotransfusion has been proven safe and effective by the predicate devices cited. The Level 1 BloodStream Recovery System is safe and effective as it employs the same method of operation (vacuum/air flow) for the same indicated use. Construction of fluid path components is of bio-compatible plastics as in the predicate devices, and as in those devices, the fluid path is sterile. The Level 1 BloodStream Recovery System may be used with the same anti-coagulant and standard blood administration sets currently used with those devices.

Patient safety is assured through the use of non-toxic materials which meet USP Class III or Class VI toxicity tests.

Aspiration handtool	PVC, Acrylic, or Polyethylene
Aspiration tubing	PVC or Polyethylene/PVC
Collection Chamber	PET, Polyethylene or Acrylic
Chamber Cap	PET or Polyethylene
Filter	Polyester/polyurethane
Filter Frame	Polypropylene
Pump Tubing	PVC
Male Luer	Acrylic
Female Luer	Co-polyester
Filter Bag	PVC
Filter Mesh	Polyester
Bag Tubing	PVC
Spike Port	PVC
Anti-Cogulant Tubing	PVC
Bag Spike	ABS

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All product will be manufactured as per GMP,s.
All fluid path components are to be assembled in a Class 100,000 clean room or better.