

Device Classification Name	RESERVOIR, BLOOD, CARDIOPULMONARY BYPASS
Regulation Number	870.4400
510(k) Number	K981284
Device Name	BETTER-BLADDER (BB)
Applicant	CIRCULATORY TECHNOLOGY, INC. 21 SINGWORTH ST. OYSTER BAY, NY 11771
Contact	YEHUDA TAMARI
Product Code	DTN
Date Received	04/08/1998
Decision Date	08/12/1998
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter	SUMMARY
Type	Traditional
Reviewed by Third Party	No

Attachment 10
Better-Bladder™
Indications for Use

510(k) Number K 98 1284
 Device Name: Better-Bladder™

Indications for Use: The Better-Bladder™ is a device that isolates pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits are made during short and long term procedures. The pressure signal can be used to control pump speed. It is also used as an inline reservoir to provide compliance in the circuit during short and long term procedures.

K 98 1284
 (Division Sign-Off)
 Division of Cardiovascular, Respiratory,
 and Neurological Devices
 510(k) Number Bette L. [Signature]