

K140321 INITARY BETTER BLADDER-PEDIATRICApr 17, 2014
58 days to decisionK140321 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k140321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Feb 18, 2014
Decision date	Apr 17, 2014
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Circulatory Technology, Inc.
Location	Oyster Bay, NY, US
Contact	YEHUDA TAMARI
510(k) history	9 submissions · 9 cleared · 1994-2014

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