FDA 510(k) Premarket Notification

K961594 BETTER-VENTER

CLEARED

Sep 5, 1996
134 days to decision

K961594 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k961594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Apr 24, 1996
Decision date	Sep 5, 1996
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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