K090878 MODIFICATION TO TERUMO'S TENDERFLOW PEDIATRIC VENOUS RETURN CANNULAE (X-COATING)

CLEARED

Apr 3, 2009
3 days to decision

K090878 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k090878/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 31, 2009
Decision date	Apr 3, 2009
Days to decision	3 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Cardiovascular Systems Corp.**
Location	Elkton, MD, US
Contact	CHRISTINA THOMAS
510(k) history	43 submissions · 43 cleared · 2000-2015