FDA 510(k) Premarket Notification

K163531 Advanced Perfusion System 1

CLEARED

Jun 7, 2017
173 days to decision

K163531 · Product code: **DTQ** · Cardiovascular
Source: https://www.510kdatabase.net/k163531/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Dec 16, 2016
Decision date	Jun 7, 2017
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Cardiovascular Systems Corporation**
Location	Elkton, MD, US
Contact	BRYAN HANN
510(k) history	29 submissions · 29 cleared · 2002-2024