FDA 510(k) Premarket Notification

K221895 Terumo Advanced Perfusion System 1

CLEARED

Apr 18, 2023
292 days to decision

K221895 · Product code: **DTQ** · Cardiovascular
Source: https://www.510kdatabase.net/k221895/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Jun 30, 2022
Decision date	Apr 18, 2023
Days to decision	292 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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