K071572 CAPIOX FX05 HOLLOW FIBER OXYGENATOR WITH INTEGRATED ARTERIAL FILTER

CLEARED

Jul 23, 2007
45 days to decision

K071572 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k071572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jun 8, 2007
Decision date	Jul 23, 2007
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Corp.**
Location	Somerset, NJ, US
Contact	GARRY A COURTNEY
510(k) history	21 submissions · 21 cleared · 1991-2010