FDA 510(k) Premarket Notification

K961000 CAPIOX SX18 HOLLOW FIBER OXYGENATOR WITH AND WITHOUT DETACHABLE HARDSHELL RESERVOIR

CLEARED

Oct 2, 1996
204 days to decision

K961000 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k961000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 12, 1996
Decision date	Oct 2, 1996
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	SANDI HARTKA
510(k) history	143 submissions · 143 cleared · 1980-2011