FDA 510(k) Premarket Notification

K802970 TERUMO HOLLOW FIBER OXYGENATOR

CLEARED

Jan 22, 1981
62 days to decision

K802970 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k802970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Nov 21, 1980
Decision date	Jan 22, 1981
Days to decision	62 days
Third-party review	No

APPLICANT

Company	**Terumo America, Inc.**
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1976-1981