FDA 510(k) Premarket Notification

K882758 CENTRIFUGAL PUMP SYSTEM LX/DX VERSION

CLEARED

Oct 13, 1988
100 days to decision

K882758 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k882758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jul 5, 1988
Decision date	Oct 13, 1988
Days to decision	100 days
Third-party review	No

APPLICANT

Company	**3M Health Care, Sarns**
Location	Mchenry, IL, US
Contact	JOSEPH W O'DONNELL
510(k) history	76 submissions · 76 cleared · 1976-1996