FDA 510(k) Premarket Notification

K854975 ELECATH PULSATILE PERFUSION PUMP

CLEARED

Jan 15, 1986
34 days to decision

K854975 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k854975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Dec 12, 1985
Decision date	Jan 15, 1986
Days to decision	34 days
Third-party review	No

APPLICANT

Company	**Electro-Catheter Corp.**
Location	Mchenry, IL, US
Contact	SILPE
510(k) history	35 submissions · 35 cleared · 1976-1995