FDA 510(k) Premarket Notification

K884390 INTERSEPT* CRYSTALLOID CARDIOPLEGIA FILTER

CLEARED

Dec 21, 1988
64 days to decision

K884390 · Product code: **KRJ** · Cardiovascular
Source: https://www.510kdatabase.net/k884390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Prebypass, Cardiopulmonary Bypass (KRJ)
Date received	Oct 18, 1988
Decision date	Dec 21, 1988
Days to decision	64 days
Third-party review	No

APPLICANT

Company	**Medtronic Blood Systems, Inc.**
Location	Anaheim, CA, US
Contact	DENNIE DYER
510(k) history	15 submissions · 15 cleared · 1988-1995