FDA 510(k) Premarket Notification

CLEARED

K921550 LIFESTREAM CENTRIFUGAL PUMP SYSTEM MODEL 2100CP

May 21, 1992
58 days to decision

K921550 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k921550/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Mar 24, 1992
Decision date	May 21, 1992
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**St. Jude Medical, Inc.**
Location	Salt Lake City, UT, US
Contact	JOSEPH CURTIS
Website	http://www.sjm.com/
510(k) history	23 submissions · 22 cleared · 1989-2018

St. Jude Medical, Inc. was a global medical device company headquartered in Little Canada, Minnesota. The company operated more than 20 principal facilities worldwide and sold products in over 100 countries. St. Jude Medical received FDA 510(k) clearances from total submissions between 1989 and 2018. The company specialized exclusively in Cardiovascular devices, establishing a focused portfolio in cardiac monitoring, catheter systems, and related interventional technologies. Founded in 1976 and publicly listed in 1977, St. Jude Medical achieved Fortune 500 status annually...