FDA 510(k) Premarket Notification

K935184 REDIFURL AND TEPERSEAL DL INTRA-AORTIC BALLOON CATHETERS WITH HYDROMER COATING

CLEARED

Feb 10, 1995
472 days to decision

K935184 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k935184/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Oct 26, 1993
Decision date	Feb 10, 1995
Days to decision	472 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**St. Jude Medical, Inc.**
Location	Salt Lake City, UT, US
Contact	SAMUEL D WADE
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...