FDA 510(k) Premarket Notification

K902159 BIFLEX(TM) ANNULOPLASTY RING

CLEARED

Jan 18, 1991
248 days to decision

K902159 · Product code: **KRH** · Cardiovascular
Source: https://www.510kdatabase.net/k902159/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ring, Annuloplasty (KRH)
Date received	May 15, 1990
Decision date	Jan 18, 1991
Days to decision	248 days
Third-party review	No

APPLICANT

Company	**St. Jude Medical, Inc.**
Location	Salt Lake City, UT, US
Contact	M ANDERSON
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...