FDA 510(k) Premarket Notification

K994171 MEDTRONIC AORTOCORONARY SHUNT AND SEPARATELY PACKAGED ARTERIOTOMY CANNULAE

CLEARED

Apr 27, 2000
139 days to decision

K994171 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k994171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Dec 10, 1999
Decision date	Apr 27, 2000
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Cardiac Surgical Products**
Location	Grand Rapids, MI, US
Contact	JAMES BALUN
510(k) history	7 submissions · 7 cleared · 2000-2003