K140165 MC2 TWO-STAGE VENOUS CANNULA, OVAL MC2 TWO-STAGE VENOUS CANNULA, THIN WALL TWO-STAGE VENOUS CANNULA, MC2X THREE-STAGE VE

CLEARED

May 20, 2014
118 days to decision

K140165 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k140165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jan 22, 2014
Decision date	May 20, 2014
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	JACQUELINE A HAUGE
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...