

K182586 DLP Aortic Root Cannula, DLP Aortic Root Cannula with Vent Line, DLP Pressure Monitoring Extension Line Adapter, DLP Cardioplegia Adapter with Pressure Port

Oct 19, 2018
29 days to decision

K182586 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k182586/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Sep 20, 2018
Decision date	Oct 19, 2018
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Linda L. Julia Davila
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,...