K132995 DLP RETROGRADE CORONARY SINUS PERFUSION CANNULA WITHOUT PRESSURE MONITORING LINE, DLP RETROGRADE CORONARY SINUS PERFUSIO

CLEARED

Oct 31, 2013
37 days to decision

K132995 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k132995/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Sep 24, 2013
Decision date	Oct 31, 2013
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	CHELSEA PIOSKE
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,...