

K133157 TRI-OPTIC MEASUREMENT CELLOct 23, 2014
371 days to decisionK133157 · Product code: **DRY** · Cardiovascular
Source: <https://www.510kdatabase.net/k133157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Oct 17, 2013
Decision date	Oct 23, 2014
Days to decision	371 days
Third-party review	No
Summary / Statement	Summary
Other names	WITH BALANCE BIOSURFACE, WITH CARMEDA BIOACTIVE SURFACE, WITH TRILLIUM BIOSURFACE, WITH 6

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	JESSICA SIXBERRY
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,...
