

**K103764 REVEAL XT INSERTABLE CARDIAC MONITOR,
MODEL 9529 AND REVEAL DX INSERTABLE CARDIAC
MONITOR, MODEL 9528**May 4, 2011
132 days to decisionK103764 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k103764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Dec 23, 2010
Decision date	May 4, 2011
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	YUKIKO CORSON
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,...