

K071641 REVEAL XTNov 21, 2007
159 days to decisionK071641 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k071641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jun 15, 2007
Decision date	Nov 21, 2007
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary
Other names	INSERTABLE CARDIAC MONITOR (MODEL 9529), PATIENT ASSISTANT (MODEL 9539)

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	MICHELLE NIVALA
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,...
