FDA 510(k) Premarket Notification

CLEARED

K203556 Medtronic Model 5492A, 5492V, 5492AL, 5492VL Patient Cables

Jul 12, 2021
217 days to decision

K203556 · Product code: **DSA** · Cardiovascular
Source: https://www.510kdatabase.net/k203556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cable, Transducer And Electrode, Patient, (including Connector) (DSA)
Date received	Dec 7, 2020
Decision date	Jul 12, 2021
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Alexandra Theisen
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,...