FDA 510(k) Premarket Notification

K190825 Medtronic Model 5392 External Pulse Generator (EPG)

CLEARED

Apr 30, 2019
29 days to decision

K190825 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k190825/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Apr 1, 2019
Decision date	Apr 30, 2019
Days to decision	29 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,...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190825/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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