

K241828 Affera Integrated Mapping SystemNov 1, 2024
130 days to decisionK241828 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k241828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jun 24, 2024
Decision date	Nov 1, 2024
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary
Other names	Impedance Localization Patch Kit

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Matthew Lobeck
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,...

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