FDA 510(k) Premarket Notification

CLEARED

K233943 Affera Mapping System (AFR-00003)

Mar 8, 2024
85 days to decision

K233943 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k233943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 14, 2023
Decision date	Mar 8, 2024
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Location Reference Patch Kit (AFR-00007); System Cart (AFR-00013)

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,...

CLINICAL EVIDENCE - NCT05120193

Treatment of Persistent Atrial Fibrillation With Sphere-9 Catheter and Affera Mapping and Ablation System

Status	Completed
Enrollment	477 patients (actual)
Study sites	23 sites
Condition studied	Atrial Fibrillation
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Jan 10, 2024
Sponsor	Medtronic Cardiac Ablation Solutions (Industry)

Primary outcome

Percent of Subjects With a Primary Adverse Event

Secondary outcome

Energy Application Time

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05120193