FDA 510(k) Premarket Notification

K253205 OptiMap Catheter - 50mm (OPTI-CATH2-50)

CLEARED

Mar 13, 2026
168 days to decision

K253205 · Product code: **MTD** · Cardiovascular
Source: https://www.510kdatabase.net/k253205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Sep 26, 2025
Decision date	Mar 13, 2026
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cortex, Inc.**
Location	Santa Clara, CA, US
Contact	Sarah Ware
510(k) history	2 submissions · 2 cleared · 2026-2026