FDA 510(k) Premarket Notification

CLEARED

K250590 MAGiC Sweep™ EP Mapping Catheter

Jul 23, 2025
146 days to decision

K250590 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k250590/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Feb 27, 2025
Decision date	Jul 23, 2025
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stereotaxis, Inc.**
Location	St. Louis, MO, US
Contact	Desmond Lewis
510(k) history	28 submissions · 28 cleared · 2002-2026

REGULATORY CONSULTANT

Consulting firm	**Access Point Technologies**
Contact	Fred Mades

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov