

K250590 MAGiC Sweep™ EP Mapping CatheterJul 23, 2025
146 days to decisionK250590 · 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 Makes |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026