July 23, 2025

Stereotaxis, Inc.
% Fred Mades
Independent Consultant
Access Point Technologies
12333 74th Avenue N
Maple Grove, Minnesota 55369

Re: K250590
Trade/Device Name: MAGiC Sweep™ EP Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: DRF
Dated: June 23, 2025
Received: June 23, 2025

Dear Fred Mades:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250590

Device Name

MAGiC Sweep™ EP Mapping Catheter

Indications for Use *(Describe)*

The MAGiC Sweep™ EP Mapping Catheter is intended for intracardiac electrophysiological recording and/or stimulation for pacing in the heart.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

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DATE PREPARED:

July 23, 2025

NAME OF MEDICAL DEVICE:

Proprietary Name: MAGiC Sweep™ EP Mapping Catheter

Common/Usual Name: Diagnostic Electrophysiology Catheter

Classification Name: Electrode Recording Catheter

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	II
Product Code:	DRF
Regulation Number:	21 CFR 870.1220

PREDICATE DEVICES:

Proprietary Name:	Niobe™ EP Catheter
Common/Usual Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Electrode Recording Catheter
510K Number:	K013484

DEVICE DESCRIPTION:

The MAGiC Sweep™ EP Mapping Catheters are biocompatible, flexible, radiopaque fixed catheters that are 130cm in length and available in multiple electrode spacing configurations and multiple magnet spacings. They have magnets encapsulated in the device shaft to allow manipulation through the vasculature and placement by a physician controlled robotic magnetic navigation system. Each device consists of 19 electrodes plus one tip electrode and come in three (3) different electrode spacings. In addition there are twenty (20) different magnet spacings for each electrode spacing configuration. The catheters are 8F diameter tapering to 5F at the distal end of the device shaft. The variety of configurations facilitate the navigation of the device to specific areas of the heart and facilitate recording of intracardiac signals and/or stimulation in the atrial and ventricular regions of the heart during electrophysiology studies.

The MAGiC Sweep™ EP Mapping Catheter is designed to be positioned in various endocardial and intravascular sites utilizing the Stereotaxis magnetic navigation system (MNS) along with the Stereotaxis catheter advancement system (CAS). The MAGiC Sweep™ EP Mapping Catheter is designed for recording intracardiac signals when connected to a recording system and for cardiac stimulation when connected to a stimulation system.

The MAGiC Sweep™ EP Mapping Catheter is comprised of a Pebax catheter shaft, platinum-iridium ring electrodes, platinum-iridium electrode tip, Neodymium Boron Magnets attached to a safety cable, and Redel electrical connectors. The Neodymium Boron Magnets are encapsulated within the catheter shaft.

INTENDED USE/INDICATION FOR USE:

The MAGiC Sweep™ EP Mapping Catheter is intended for intracardiac electrophysiological recording and/or stimulation for pacing in the heart.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

Technologically the MAGiC Sweep™ EP Mapping Catheter is similar to Stereotaxis Niobe™ Catheter in terms of indications for use, design, materials, technology and performance. Both catheters have shafts comprised of thermoplastic elastomer and platinum-iridium electrodes. Both catheters contain magnets encapsulated in the device shaft. Both catheters are identical in length. The MAGiC Sweep™ EP Mapping Catheter has an 8F diameter tapering to 5F, while the Niobe™ Catheter has a 7F distal shaft diameter. The MAGiC Sweep™ EP Catheter has a total of 20 (1 tip, 19 ring) electrodes whereas the Niobe™ has a total of 2 (1 tip, 1 ring) electrodes. The MAGiC Sweep™ EP Catheter is available in 3 different electrode spacings and 20 different magnet spacings, whereas the Niobe™ Catheter is available in only a single configuration. The various combinations of electrode spacing and magnet spacing in MAGiC Sweep™ EP Mapping Catheter facilitate the capability of the device to reach specific areas in the targeted chambers of the heart.

BENCH TESTING PERFORMED

The MAGiC Sweep™ EP Mapping Catheter was thoroughly tested based on existing standards and test methods. These tests include visual, dimensional, electrical performance - continuity, leakage impedance, dielectric; mechanical performance – tensile, torque, deflection, shaft buckling, radio-detectability, corrosion; biocompatibility (short term <24 hours, blood contacting) and packaging. Testing demonstrates that the MAGiC Sweep™ EP Mapping Catheter met the specifications and is substantially equivalent to the predicate.

ANIMAL TESTING

The MAGiC Sweep™ EP Mapping Catheter was utilized in an animal studies (porcine model) using the Stereotaxis GenesisX™ and Genesis™ magnetic navigation systems. During the studies the catheter was advanced, positioned and successfully mapped the left and right ventricles and left and right atriums of the heart.

TESTING RESULTS

During both Bench Testing and Animal Testing there were no new questions raised regarding safety or effectiveness of the MAGiC Sweep™ EP Mapping Catheter.

CONCLUSIONS

The MAGiC Sweep™ EP Mapping Catheter is substantially equivalent in design, materials, sterilization, principles of operation, performance and intended use to the Niobe™ EP Catheter.