



November 6, 2025

Stereotaxis, Inc.
Angela McKnight
Senior Regulatory Affairs Specialist
710 Tucker Blvd, Suite 110
Saint Louis, Missouri 63101

Re: K251792

Trade/Device Name: Stereotaxis GenesisX RMN with Navigant™ Workstation (NWS)
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II
Product Code: DXX
Dated: June 11, 2025
Received: October 8, 2025

Dear Angela McKnight:

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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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251792

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Please provide the device trade name(s).

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Stereotaxis GenesisX RMN with Navigant™ Workstation (NWS)

Please provide your Indications for Use below.

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GenesisX RMN:

- The GenesisX RMN is intended to navigate compatible magnetic devices in the chambers of the heart and arterial and venous vasculature by orienting the device tip in a desired direction.

Please select the types of uses (select one or both, as applicable).

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

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510(k) Summary [21 CFR 807.92]

Submitter

Name and Address: Stereotaxis, Inc.
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**Establishment
Registration Number:**

Primary Contact: Angela McKnight
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Date Prepared: June 11, 2025

Device Information

Device Name: Stereotaxis GenesisX RMN with Navigant™ Workstation (NWS)

**Classification/
Common Name:** Steerable Catheter Control System

Classification: II

Product Code: DXX

Regulation Number & Name: 21 CFR 870.1290

Classification Panel: Cardiovascular

Predicate Information

	510(k) Number	Trade Name	Product Class	Product Code
Primary Predicate	K021555	Niobe Magnetic Navigation System	II	DXX
Reference Device	K193147	Genesis RMN	II	PJB, NDQ

Device Description

Stereotaxis GenesisX RMN with Navigant™ Workstation (NWS) and Cardiodrive® System (GenesisX) is an interventional workstation for the intravascular navigation of appropriately equipped, magnetically

adapted, devices (e.g., catheters or guidewires) using computer-controlled permanent magnets to orient or steer the tip of a magnetic device, and remotely advance and retract only compatible magnetic electrophysiology (EP) catheters inside the patient's heart. GenesisX incorporates software that determines the direction the magnetic field should be applied based on physician interaction with the user interface devices.

Intended Use / Indications for Use

The Indications for Use / Intended Use are provided below:

GenesisX RMN:

- The GenesisX RMN is intended to navigate compatible magnetic devices in the chambers of the heart and arterial and venous vasculature by orienting the device tip in a desired direction.

Substantial Equivalence

GenesisX RMN has the same intended use as Niobe MNS (K021555, cleared January 15, 2003). GenesisX RMN is substantially equivalent in design and functionality to Niobe MNS and is similar in design and functionality to the reference device Genesis RMN (K193147, cleared March 5, 2020). GenesisX RMN, Niobe MNS and Genesis RMN are designed with two magnets located on the opposite sides of a patient table whose orientation is coordinated by software and hardware controls. During navigation the two magnets work together to produce a composite magnetic field in the desired direction. The main difference of GenesisX RMN relative to Niobe MNS and Genesis RMN is the lower operating field strength due to its use of smaller permanent magnets. In addition to smaller magnets, GenesisX uses a slightly different form factor for the electromechanical design of the articulating arms, but still utilizes common industrial components found in many medical systems (e.g., imaging systems, patient tables, etc.).

Design verification and validation testing of GenesisX RMN was conducted to show substantial equivalence to the predicate device. Testing conducted was identified on the basis of risk analysis activities performed to evaluate the impact of the modification on the device. Testing activities included electrical safety, functional performance and cybersecurity penetration tests.

Risk analysis activities were completed based on ISO 14971. Electrical/mechanical device safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1 and 60601-1-2.

The modifications do not introduce or raise different questions about the safety or effectiveness of the device. The fundamental technological characteristics and principle of operation of the GenesisX are unchanged from the predicate devices. The GenesisX is substantially equivalent to the predicate device in intended use, design, performance, and technological characteristics.

Performance Data

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical testing.

Test results demonstrate that GenesisX meets specifications and performs as intended. No new safety or performance issues were raised during testing. GenesisX is substantially equivalent to the predicate device.

Conclusion

Based upon the documentation presented in this 510(k) it has been demonstrated that the GenesisX device is safe and effective for its intended use and GenesisX is substantially equivalent to the predicate devices Niobe MNS (K021555).