August 27, 2026

Stereotaxis, Inc.
Angela Mcknight
Primary Correspondent
710 Tucker Blvd., Suite 110
St. Louis, Missouri 63101

Re: K262744
Trade/Device Name: GenesisX RMN
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable catheter control system
Regulatory Class: Class II
Product Code: DXX
Dated: July 31, 2026
Received: August 3, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MARCO CANNELLA -S

Marco Cannella Ph.D.
Acting Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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.	K262744

Please provide the device trade name(s).

GenesisX RMN

Please provide your Indications for Use below.

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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary [21 CFR 807.92]

Submitter

Name and Address: Stereotaxis, Inc.
710 N. Tucker Blvd.
Suite 110
St. Louis, MO 63101

Establishment Registration Number: 3003084417

Primary Contact: Angela McKnight
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Date Prepared: July 31, 2026

Device Information

510(k) Number: K262744

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

Common Trade Name: GenesisX RMN

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
Predicate Device	K251792	GenesisX RMN	II	DXX

Device Description

GenesisX RMN is an interventional workstation for the intravascular navigation of appropriately equipped, magnetically adapted devices (e.g., catheters or guidewires) through the vasculature to designated target sites. GenesisX RMN uses computer-controlled permanent magnets to generate magnetic fields that orient or steer the tip of a magnetic device. It incorporates software that determines the direction the magnetic field should be applied based on physician interaction with the user interface devices. GenesisX RMN works with Cardiodrive to advance and retract compatible ablation and mapping catheters.

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, as approved under K251792, utilized software integration with specific digital fluoroscopy systems to prevent collisions between the RMN and fluoroscopy systems. In this submission, GenesisX RMN is being modified with passive mechanical restraints that limit fluoroscopy system angulation when the GenesisX RMN system is in use. These restraints activate existing collision-avoidance sensors built into the fluoroscopy system. The GenesisX user-interface was concurrently updated to ensure user awareness and confirmation that the fluoroscopy system is positioned appropriately prior to bringing the RMN system into its active position. The user-interface updates are only applicable during the process of moving the RMN system from its stowed to the active position, with no changes made to the user experience during procedural navigation.

This update to the GenesisX RMN system does not introduce any change to the indication for use. It does not impact clinical performance, nor introduce any change in the user experience during procedural navigation. The restraints are passive and introduce no electrical changes. The GenesisX RMN risk assessment was updated, and no critical risks were left unmitigated. Human factor testing was performed to ensure use of the restraints and the UI prompts were clear and effective.

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

Conclusion

Based upon the documentation presented in this 510(k) it has been demonstrated that the modifications to GenesisX RMN approved under K251792 do not affect the safety and efficacy for its intended use.