March 5, 2020

Stereotaxis, Inc.
Kenneth Lock
Vice President, Clinical, Regulatory and Quality
4320 Forest Park Avenue, Suite 100
St. Louis, Missouri 63108

Re: K193147
Trade/Device Name: Stereotaxis Genesis RMN with Navigant Workstation (NWS) and Cardiodrive System (Genesis MNS)
Regulation Number: 21 CFR 870.5700
Regulation Name: Steerable Cardiac Ablation Catheter Remote Control System
Regulatory Class: Class II
Product Code: PJB, NDQ
Dated: February 1, 2020
Received: February 3, 2020

Dear Kenneth Lock:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Mark Fellman
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193147

Device Name

Stereotaxis Genesis RMN® with Navigant™ Workstation (NWS) and Cardiodrive® System (Genesis MNS)

Indications for Use *(Describe)*

Genesis MNS is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature, neurovascular and peripheral vasculature by orienting the device tip in a desired direction.

The Cardiodrive® Catheter Advancement System (CAS) is intended to automatically advance and retract compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis MNS.

The Cardiodrive® system is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

The Cardiodrive® system is not intended to advance or retract non-compatible catheters and/or other non-compatible devices into the neurovasculature.

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.

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510(k) Summary per 21CFR §807.92

Submitter's information

Stereotaxis, Inc.
4320 Forest Park Ave, Suite 100
St. Louis, MO 63108
Contact: Kenneth Lock, Vice President, Clinical, Regulatory and Quality
Telephone: 314-678-6123

Device/ classification name

Device Name:	Genesis RMN® with Navigant™ Workstation (NWS) and Cardiodrive® System (Genesis MNS)
Classification/Common name:	Steerable cardiac ablation catheter remote control system.
Classification Number:	870.5700
Product Code:	PJB
Classification Panel:	Cardiovascular
Predicate Devices:	Niobe MNS (K192775)

Device description

Stereotaxis Genesis RMN® with Navigant™ Workstation (NWS) and Cardiodrive® System (Genesis MNS) is an interventional workstation for the intravascular navigation of appropriately equipped, magnetically adapted, devices (e.g., catheters or guidewires) through tissue to designated target sites 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) mapping and ablation catheters inside the patient's heart. Genesis MNS incorporates software that determines the direction the magnetic field should be applied based on physician interaction with the user interface devices.

Intended use

Genesis MNS is intended to navigate compatible magnetic devices through tissue to designated target sites in the right and left heart and coronary vasculature, neurovascular and peripheral vasculature by orienting the device tip in a desired direction.

The Cardiodrive® Catheter Advancement System (CAS) is intended to automatically advance and retract compatible magnetic electrophysiology (EP) mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis MNS.

The Cardiodrive® system is not intended to advance the EP mapping and ablation catheters through the coronary vasculature or the coronary sinus.

The Cardiodrive® system is not intended to advance or retract non-compatible catheters and/or other non-compatible devices into the neurovasculature.

Technological Characteristics

	SUBJECT DEVICE Stereotaxis Genesis RMN® with Navigant™ Workstation (NWS) and Cardiodrive® System	PREDICATE DEVICE Stereotaxis Niobe MNS with Navigant NWS, and Cardiodrive K183027, K192775
Magnet System		
Type of Magnets	Permanent, Positioned Mechanically, metal alloy	Permanent, Positioned Mechanically, metal alloy
Magnet Position	Permanent, Positioned Mechanically	Permanent, Positioned Mechanically
Navigation Volume	6 inch B field Sphere	6 inch B field Sphere
Magnet System Design	Center of Mass design no floor track	Cantilevered with floor track
Magnet Weight and Size	640 lb	764 lb
Distance from Magnet to Cover	8.17 mm	74 mm
Response Time	Faster – movement from center less momentum	Slower- larger motion heavier magnet more momentum
Articulating Arms	Biceps and forearm shoulder	Track mounted arc and fixed position
Base Tilt Sensing	Available with continuous sensing	Not available
Control Cabinet	81.7” (H) X 30.4” (W) X 32.1” (D)	84.5”(H) x 59.1” (W) x 23.6” (D)
Control of Steerable Device Orientation	Remote and Computer Control	Remote and Computer Control
Devices Controlled by System	Specially Designed Magnetic Catheters and Guidewires	Specially Designed Magnetic Catheters and Guidewires
Adjusts Magnetic Field	Based on information received from Navigant NWS Software	Based on information received from Navigant NWS Software
Operating Magnetic Field Strength	0.08-0.12 Tesla	0.08-0.12 Tesla
Magnet Positioners		
Number, Location	2, positioned on right and left side of patient	2, positioned on right and left side of patient
Magnet Covers		
Material	Fiberglass	Fiberglass
Sensors	Yes, Contact Sensors	Yes, Contact Sensors
Magnetic Field Modes and Positions		
Magnetic Field Modes	Applied, Reduced, Stowed	Applied, Reduced, Stowed
Magnetic Field Positions	Stowed, Pivoted, Retracted, Navigate AP, Navigate LAO, Navigate RAO	Stowed, Pivoted, Retracted, Navigate AP, Navigate LAO, Navigate RAO
NAVIGANT NAVIGATION WORKSTATION		
User Interface Components		
Navigant Software	V5.0.6	V5.0.6
Tableside Magnet Controller	1, Located on the patient table accessory rail	1, Located on the patient table accessory rail
Mouse	1, Standard PC compatible wheel Mouse	1, Standard PC compatible wheel Mouse
Keyboard	1, Standard PC compatible Keyboard (without integrated keypad functions)	1, Standard PC compatible Keyboard (without integrated keypad functions)
Keypad	1, **S**eparate component, contains the keys from the predicate keyboard	1, Separate component, contains the keys from the predicate keyboard
Display Monitors, Location	1+ (User preference),	1+ (User preference),

	SUBJECT DEVICE Stereotaxis Genesis RMN® with Navigant™ Workstation (NWS) and Cardiodrive® System	PREDICATE DEVICE Stereotaxis Niobe MNS with Navigant NWS, and Cardiodrive K183027, K192775
	Procedure and Control Rooms	Procedure and Control Rooms
Procedure Types		
Electrophysiology (EP)	Yes	Yes
Interventional Cardiology (IC)	Yes	Yes
Cardiac Resynchronization Therapy (CRT)	Yes	Yes
Interventional Radiology (IR)	Yes	Yes
Interventional Neuroradiology (INR)	Yes	Yes
Control Panels		
Clinical Workflow Manager (CWM)	Optional use feature that acts as a map and allows a physician to work their way through an entire procedure	Optional use feature that acts as a map and allows a physician to work their way through an entire procedure
Control Panel - Navigations	• Pre-set navigations • Stored navigations • Rename stored navigations Delete stored navigations	• Pre-set navigations • Stored navigations • Rename stored navigations Delete stored navigations
Control Panel - Visible Objects	• Delete • Edits geometry • Right-click menu for vessels • Vessel properties • Manual vessel registration Carto colors and Carto tags	• Delete • Edits geometry • Right-click menu for vessels • Vessel properties • Manual vessel registration Carto colors and Carto tags
Control Panel - Bullseye Targeting	• Bullseye target colors • Altering bullseye targeting Bullseye targeting automation	• Bullseye target colors • Altering bullseye targeting Bullseye targeting automation
Control Toolbars		
Control Toolbar – Main	Title Bar, Status Bar, Reference Images	Title Bar, Status Bar, Reference Images
Control Toolbar – Hardware	Status Indicator	Status Indicator
User Views		
Pre-operative Navigation	Included	Included
3D Constellation	Included	Included
3D Anatomic	Included	Included
Navigation Fluoroscopy Images	Included	Included
Display Graphics on Live Fluoroscopy		
Field Mode Indicator	Included	Included
Magnetic Fields	Included	Included
Reduced Fields	Included	Included
Virtual Catheter	Included	Included
Points and Constellations	Included	Included
Pre-Op Data		
Load, Register, and Display Pre-operative Data	Included	Included
IC Touch Supports		

	SUBJECT DEVICE Stereotaxis Genesis RMN® with Navigant™ Workstation (NWS) and Cardiodrive® System	PREDICATE DEVICE Stereotaxis Niobe MNS with Navigant NWS, and Cardiodrive K183027, K192775
Apply and Reduce Magnetic Field	Included	Included
Image Transfer	Included	Included
3D Anatomic, 3D Constellation, Naviline Fluoroscopy	Included	Included
Automation		
Click and Go Targeting	Included	Included
Naviline	Included	Included
Auto-mapping	Included	Included
Ablation History		
Ablation History Graph Display	Included	Included
Ablation History Volume Display	Included	Included
Required Companion System		
Digital Fluoroscopy	Compatible with Omega and Siemens	Compatible with Omega, Siemens and Philips
Physician Preference Companion Devices and Systems		
Odyssey Workstation	FDA-cleared, compatible	Included
Compatibility with updated firmware for integrated video component	Included	Included
Vdrive Robotic Navigation System	FDA-cleared, compatible	Included
Cardiodrive Catheter Advancement System (CAS)	FDA-cleared, compatible	Included
Cardiodrive Catheter Advancement System (CAS)	Included	Included
Mapping Systems	FDA-cleared, compatible system Carto, and AcQmap	Included
User Interface	Included	Included
Ablation Catheters	FDA-approved, magnetic compatible	Same

Performance data

Performance data establish the substantial equivalence of the Genesis MNS including software verification and validation data, bench performance testing and animal testing. Performance testing was conducted for electrical safety, and EMC compatibility.

Animal Testing: Stereotaxis performed an animal study in a porcine model to evaluate the safety and effectiveness of Genesis MNS to perform movements of multiple compatible ablation catheters, safety features, and mechanical performance testing according to the Special Controls. This study demonstrated that the Genesis MNS met its performance requirements.

Based upon the documentation presented in this 510(k) it has been demonstrated that the Genesis MNS device is safe and effective for its intended use.

Special Controls

Special Controls	How Special Control Has Been Met
1) Non-clinical mechanical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be performed: i. Mechanical performance of the system (without catheter connected);	Using the proposed device, Magnetic field performance testing without the catheter connected. Testing included: • a robotic field accuracy survey. • reduced field mode • angular resolution • isocenter offset (for heart position) Field characteristics (strength, direction, position and accuracy) meet the same requirements for the predicate Niobe and the subject Genesis.
ii. Mechanical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following: (A) Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and	*Manual Control Performance Testing* Performance testing data for the reference Niobe device included deflection testing, accuracy testing with target phantom and anatomical position testing with a plastic heart model. The results of this testing provide mechanical performance data for the reference device. *Remote Control Performance Testing* The same performance testing of compatible devices was performed with the subject Genesis system that included deflection testing, accuracy testing with target phantom and anatomical position testing with a plastic heart model. The results of this testing provide mechanical performance data for the reference device. The subject Genesis system performed at the same level with compatible devices as the predicate Niobe System. The subject device generates the same magnetic fields as the predicate device. The compatible catheter performance testing results were the same for Genesis as it was for Niobe and demonstrates substantial equivalence.
(B) Evaluation of the accuracy and function of all device control safety features; and	Testing of the four primary safety controls related to the physical motion of the system was conducted on the proposed device. These concern physical movement of the magnet positioners, movement of the covers toward the patient, continuous advancement of the catheter, and motion e-stops. All safety controls passed the test. Successful user testing of safety controls was the same between Niobe and Genesis. Genesis is substantial equivalent to the predicate device in relation to the accuracy and function of the device control safety features.
iii. Simulated-use testing in a bench anatomic model or animal model.	Validation testing for Genesis includes use testing of clinical workflows in a bench model. An animal study was performed that employed typical clinical workflows including compatibility with mapping system, CardioDrive, and fluoroscopy. Clinical workflow testing for Genesis with compatible devices was the same

Special Controls	How Special Control Has Been Met
	as Niobe. Animal and simulated use testing provided objective evidence to substantiate that the Genesis MNS is substantially equivalent to the predicate device.
2. Non-clinical electrical testing must include validation of electromagnetic compatibility (EMC), electrical safety, thermal safety, and electrical system performance. The following performance testing must be performed: i. Electrical performance of the system with compatible catheters connected to verify that the system does not impact catheter function or performance. Assessments must include the following: A. Side-by-side remote control and manual comparisons of catheter manipulation (including all ranges of motion of catheter deflection and tip curl) for all compatible catheters; must include testing for worst-case conditions, and	**Manual Control Performance Testing** EMC and Electrical safety testing showing conformance with IEC 60601 were performed by TuV for the reference Niobe device. **Remote Control Performance Testing** EMC testing for the proposed device hardware demonstrating conformance with IEC 60601-1-2 was performed by Intertek. As required, both the predicate device and proposed device were tested according to IEC 60601-1-2 standards by Nationally Recognized Testing Labs. All tests passed.
B. Evaluation of the accuracy and function of all device control safety features; and	Electrical safety testing on the proposed device demonstrating compliance with IEC 60601, and IEC 60601-1-2 was performed by Intertek.
ii. Electrical safety between the device and ablation catheter system and with other electrical equipment expected in the catheter lab or operating room.	The proposed system has been tested for compatibility with specific x-ray, ablation generators, and mapping systems. In addition, electrical isolation and emissions testing have been performed by Intertek.

<table>
<tr><th>Special Controls</th><th>How Special Control Has Been Met</th></tr>
<tr><td>3. In vivo testing must demonstrate that the device performs as intended under anticipated conditions of use, including an assessment of the system impact on the functionality and performance of compatible catheters, and documentation of the adverse event profile associated with clinical use. Evidence must be submitted to address the following:
i. Manipulation and Positioning: Ability to manipulate compatible catheters to pre-specified cardiac locations and conform proper anatomic placement and tissue contact, in accordance with the system indications for use and compatible catheter indications for use;</td><td>Animal study was conducted with compatible devices to demonstrate compatibility. Catheters were directed to predefined targets and evidence of suitable contact was demonstrated.
In vivo testing was conducted with the subject device and all compatible devices functioned in a similar manner to the predicate device. This testing is equivalent to the testing performed for the predicate device. This demonstrates that the subject device is substantially equivalent to the predicate device with compatible catheters.</td></tr>
<tr><td>ii. Safety: Assess device-related complication rate and major procedural complication rate (regardless of device relatedness) in comparison to literature and/or manual comparison group for compatible ablation catheters to support the indications for use;</td><td>The subject device generates the same magnetic fields as the predicate device and works with the same compatible fluoroscopic, mapping and ablation devices. Existing magnetic navigation clinical data are still relevant. The following information is sufficient enough to demonstrate substantial equivalency to the predicate device.
Clinical data to support the safety of the Magnetic Navigation System, which includes Niobe, Navigant Software, the CardioDrive catheter advancement system and a compatible ablation catheter, was reviewed.
The following is a summary of data from clinical studies sponsored by Stereotaxis that have been submitted to the FDA in three separate submissions:
P050029 Helios II ablation catheter (ATTRAC, ATTRAC II and HEART)
K071029 CardioDrive with Ablation Catheter (ATTRAC II)
K140804 V-CAS (VERSATILE)
A total of 511patients from 4 studies were enrolled using the Niobe Magnetic Navigation System, which included the Niobe MNS, CardioDrive, a Magnetic Ablation Catheter, and the Navigant Software.

The following table describes the major complication rates reported in these trials.
<table>
<tr><th>Study</th><th>RMN Patients</th><th>7 Day Major Complication</th></tr>
<tr><td>ATTRAC</td><td>182</td><td>7/182 (3.8%)</td></tr>
<tr><td>ATTRAC II</td><td>80</td><td>1/80 (1.3%)</td></tr>
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<table>
<tr><th>Special Controls</th><th>How Special Control Has Been Met</th></tr>
<tr><td></td><td>
<table>
<tr><td>HEART Study</td><td>129</td><td>7/129 (5.4%)</td></tr>
<tr><td>VERSATILE</td><td>120</td><td>5/120 (4.2%)</td></tr>
<tr><td>Total</td><td>511</td><td>20/511 (3.9%)</td></tr>
</table>
</td></tr>
<tr><td>iii. Efficacy: Assess ablation success in comparison to literature and/or a manual comparison group for compatible ablation catheters to support the indications for use; and</td><td>The subject device generates the same magnetic fields as the predicate device and works with the same compatible fluoroscopic, mapping and ablation devices. Existing magnetic navigation clinical data are still relevant. The following information is sufficient enough to demonstrate substantial equivalency to the predicate device.

Data to support the ablation success of the Magnetic Navigation System which includes Niobe, Navigant Software, the CardioDrive catheter advancement system and a compatible ablation catheter was reviewed. The following is a summary of data from clinical studies sponsored by Stereotaxis that have been submitted to the FDA in three separate submissions:
• P050029 Helios II ablation catheter (ATTRAC ,ATTRAC II and HEART study)
• K071029 CardioDrive with Ablation Catheter (ATTRAC)
• K140804 V-CAS (VERSATILE)
A total of 511 patients from 4 studies were enrolled using the Niobe Magnetic Navigation System, which included the Niobe MNS, CardioDrive, a Magnetic Ablation Catheter, and the Navigant software. The ATTRAC study series and the HEART Study used the Helios ablation catheter, and the Versatile study used the BWI RMT Thermocool catheter. The following table describes the acute and 90-day success rates reported in these trials.
<table>
<tr><th>Study</th><th>RMN Patients</th><th>Acute Success RMN</th><th>90 day success RMN</th></tr>
<tr><td>ATTRAC</td><td>182</td><td>175/182 (96.2%)</td><td>145/147 (98.6%)</td></tr>
<tr><td>ATTRAC II</td><td>80</td><td>71/75 (94.7%)</td><td>51/54 (94.4%)</td></tr>
<tr><td>HEART Study</td><td>129</td><td>108/121 (89.3)</td><td>82/87 (94.3%)</td></tr>
<tr><td>VERSATILE</td><td>120</td><td>119/120 (99.2%)</td><td>Not reported</td></tr>
<tr><td>Total</td><td>511</td><td>473/498 (95.0%)</td><td>278/288 (96.5%)</td></tr>
</table>
</td></tr>
<tr><td>iv. User assessment of device remote controls and safety features.</td><td>The same user assessment testing of the predicate device was performed with the subject device and all safety features passed testing. This is sufficient to demonstrate substantial equivalency to the predicate device with regard to the safety controls.</td></tr>
<tr><td>4. Post-market surveillance (PMS) must be conducted and completed in accordance with FDA agreed upon PMS protocol.</td><td>The subject device generates the same magnetic fields as the predicate device and works with the same compatible fluoroscopic, mapping and ablation devices. Existing magnetic navigation clinical data are still relevant. The following information is sufficient enough to demonstrate substantial equivalency to the predicate device.</td></tr>
</table>

Special Controls	How Special Control Has Been Met
	Given the amount of clinical data from submitted studies and peer reviewed publications for magnetic navigation, a post market surveillance study is not warranted. The following summarizes the overwhelming evidence available to support the safety and efficacy of the MNS system: • Four studies submitted to the FDA demonstrated a major adverse event rate of 3.9%. Data from these four studies supported 510(k) clearances for K071029, and K140804 and PMA approval in P050029. • Acute success and 90 success rates were 95.0% and 96.5% respectively in those studies • More than 8,000 patients were reported in the literature using the MNS System with a major complication rate of 0.72% compared to a manual rate of 2.1% • Acute success rates and long-term success rates were similar in both the MNS and manual groups Stereotaxis proposes to continue monitoring the safety and efficacy of the Genesis System through the literature and Post Marketing Surveillance program.
5. A training program must be included with sufficient educational elements that, upon completion of the training program, the clinical and supporting staff can: i. Identify the safe environments for device use, ii. Use all safety features of the device, and iii. Operate the device in simulated or actual use environments representative of indicated environments and use for the indication of compatible catheters.	Representatives from the company train the physician and staff in the use of the Genesis Magnetic Navigation system using simulator and phantom testing. The Genesis User's Manual provides detailed operating instructions on the system and the navigation software. This information is reviewed with the physician and staff during simulation sessions and phantom training with the actual system
6. Performance data must demonstrate the sterility of the sterile disposable components of the system	The Genesis System is not provided in sterile form nor is it required to be sterilized prior to use, therefore, sterilization information is not applicable. The Genesis System does not include sterile disposable components as part of the system. CardioDrive includes a single-use disposable (QuikCAS) to interface with the compatible ablation catheter. The sterile components underwent sterilization testing. All sterilization testing resulted in a PASS.

Special Controls	How Special Control Has Been Met
7. Performance data must support shelf life by demonstrating continued sterility of the device (of the sterile disposable components), package integrity, and device functionality over the requested shelf life.	The Genesis System is not provided in sterile form nor is it required to be sterilized prior to use, therefore, shelf life information, including package integrity and function of the device over the stated shelf life are not applicable. CardioDrive includes a single-use disposable (QuikCAS) to interface with the compatible ablation catheter. The sterile components underwent shelf-life /packaging and sterilization testing. All sterilization and packaging testing resulted in a PASS, and each component was validated for a shelf life of 3 years.
8. Labeling must include: i. Appropriate instructions, warnings, cautions, limitations, and information related to the intended patient population, compatible ablation catheters, and the device safeguards for the device; ii. Specific instructions and clinical training needed for the safe use of the device, which includes: A. Instructions on assembling the device in all available configurations, including installation and removal of compatible catheters;	Genesis User's Manual includes: • Compatible Catheters • Indications for Use • Warnings • Safety Controls The Genesis System does not require assembly of the device prior to use. The Genesis System is considered permanent equipment installed in a Stereotaxis Magnetic Navigation Lab. Stereotaxis performs all installation activities for each Genesis System; therefore, assembly and installation instructions to the physician user are not required. With regard to use of magnetically-compatible devices with the Genesis System, assembly and installation of these devices to/with the Genesis System is not required. Magnetically-compatible catheters interface with the CardioDrive CAS device which advances and retracts the device and instructions related to the catheter-CAS interface are provided in the CardioDrive instructions for use. The Genesis System only applies a magnetic field to orient the distal tip of a magnetically-compatible device; therefore, the manipulation of the distal end of the device is by indirect (non-physical) means for which assembly or installation of other devices is not required.

Special Controls	How Special Control Has Been Met
B. Instructions on all available modes or states of the devices; C. Instructions and explanation of all controls, inputs, and outputs D. Instructions on all safety features of the device and E. Validated methods and instructions for reprocessing/disinfecting any reusable components	The Genesis System User Guide includes an explanation and instructions for the following, controls, modes, and states of the device: • Procedure room components • System positions • Tableside Magnet Controller • System power up • Cover Force Sensor • Navigation Position Assistance • Software Basic Information • CardioDrive CAS user interface • Activation codes The Genesis System is a medical device that does not have any reusable components that reprocessing or disinfection prior to use. The magnet pods are covered by drapes during the procedure and may be wiped clean using hospital-grade EPA-registered germicide solutions following each procedure. Cleaning instructions are provided in the "Cleaning the Genesis System" section of the Genesis System User Guide).
iii. A detailed summary of the mechanical compatibility testing including: A. A table with a complete list of compatible catheters tested (manufacturer trade name and model number), and B. A table with detailed test results, including type of test, acceptance criteria, and test results (i.e., pass for meeting acceptance criteria);	- Biosense Webster Navistar RMT - Biosense Webster Navistar RMT Thermocool - Biosense Webster Celsius RMT - Biosense Webster Celsius RMT Thermocool Mechanical testing for both the predicate device and the subject device included accessing pre-defined geometric targets from multiple positions with each of the compatible catheters. Testing also included anatomical phantom navigation to pre-defined anatomical targets with each of the compatible catheters. All tests passed successfully. The subject device demonstrated substantial equivalence to the predicate device.
iv. A detailed summary of the in vivo testing including: A. A table with a complete list of compatible catheters used during testing (manufacturer trade name and model number);	- Biosense Webster Navistar RMT - Biosense Webster Navistar RMT Thermocool - Biosense Webster Celsius RMT - Biosense Webster Celsius RMT Thermocool In vivo testing was performed with the subject device that included the listed compatible catheters. In the subject device, all compatible catheters functioned in a similar manner to the predicate device. The Genesis system provides the same magnetic field and works with the same CardioDrive

Special Controls	How Special Control Has Been Met
	system as Niobe.
B. Adverse events encountered pertinent to use of the device under use conditions;	The Genesis system provides the same magnetic field, works with the same CardioDrive system and same compatible catheters as Niobe. Performance data has shown that the catheters respond to the field in the same manner. Data from four clinical studies involving 511 patients who underwent catheter ablation using the Stereotaxis Magnetic Navigation System (MNS) are summarized. Collectively, the data in these studies demonstrates the safety and effectiveness of the Magnetic Navigation System for catheter ablation. Study Design: All four studies were prospective in nature and included safety endpoints. Data from all four studies were used to support regulatory approvals. Evaluation of 7 day major adverse events for safety is reported. Study Results: Adverse Events: The overall 7 day major complication rate for all four studies was 20/511 (3.9%) Major adverse events that occurred within 7 days post procedure included: • 1 cardiac tamponade related to right sided catheter • 1 cardiac tamponade related to the transseptal puncture • 1 new focal wall abnormality • 1 change in LVEF (60% to 45-50%) • 2 vena cava thrombi • 1 groin complication • 1 chest soreness • 1 prolonged hospitalization for grogginess • 1 pseudoaneurysm • 1 bleeding • 1 anemia • 1 dementia • 1 pericardial effusion • 1 heart block requiring pacemaker • 2 pulmonary embolisms • 1 AV fistula • 2 arrhythmia recurrence (per protocol requirements)

<table>
<tr><th>Special Controls</th><th>How Special Control Has Been Met</th></tr>
<tr><td></td><td>Conclusion

The data in this summary support the reasonable assurance of safety and effectiveness of the Stereotaxis Magnetic Navigation System for cardiac ablation procedures.

These data have been summarized in the Genesis User's Guide.</td></tr>
<tr><td>C. A detailed summary of device- and procedure-related complications; and</td><td>The following listing of the procedure related complications have been reported in clinical trials submitted to the agency:
Two (2) patients out of 177 (1.1%) had an acute major adverse event and 5/182 (2.7%) had a major adverse event within 7 days of ablation in the ATTRAC Study. There was 1 death reported in the study secondary to respiratory failure, unrelated to the device. No cardiac tamponades or perforations were reported. One patient experienced a groin complication, two patients experienced vena cava thrombi, one experienced chest soreness, and one had a prolonged hospitalization due to being groggy. There were no device related adverse events.

In the ATTRAC II Study, 1/80 (1.3%) patient had a major adverse event which was a cardiac tamponade due to a right sided non-study catheter. There were no deaths reported in this study. There were no device related adverse events.

In the HEART study, the overall acute major adverse event rate was 5.4% for the magnetic arm. No deaths or cardiac tamponades were reported. There was 1 pericardial effusion, 1 heart block requiring pacemaker, 2 pulmonary embolisms, 1 AV fistula, and 2 arrhythmia recurrences (considered a major adverse event per the protocol) in the magnetic arm of the study. All were reported as device or procedure related adverse events.

The overall major adverse event rate in the VERSATILE Study was 5/120 (4.2%) in this study. There was one cardiac tamponade, one pseudo aneurysm, one bleeding, one patient presented with anemia and dementia. The cardiac tamponade event started as a pericardial effusion and progressed into cardiac tamponade due to the transseptal puncture. The DSM adjudicated these events to be possibly and probably related to the procedure, respectively. There were no device related adverse events.</td></tr>
<tr><td>D. A summary of study outcomes and endpoints. Information pertinent to the fluoroscopy times/exposure for the procedure, patient, and operator fluoroscopic exposure;</td><td>The following table summarizes the acute and long term success rates as well as fluoroscopy times reported in the clinical trials.
<table>
<tr><th>Study</th><th>RMN Patients</th><th>Acute Success RMN</th><th>90 day success RMN</th><th>Mean Fluoroscopy time
Mean +/-S.D
[range]</th></tr>
<tr><td>ATTRAC</td><td>182</td><td>175/182 (96.2%)</td><td>145/147 (98.6%)</td><td>15.89+/-13.15
[1.05, 66.5]</td></tr>
</table></td></tr>
</table>

Special Controls	How Special Control Has Been Met
	<table><tr><td>ATTRAC II</td><td>80</td><td>71/75 (94.7%)</td><td>51/54 (94.4%)</td><td>10.64 +/-9.78 [0.63,61.0]</td></tr><tr><td>HEART Study</td><td>129</td><td>108/121 (89.3)</td><td>82/87 (94.3%)</td><td>16.91 +/- 9.92 [3.13,44.18</td></tr><tr><td>VERSATILE</td><td>120</td><td>119/120 (99.2%)</td><td>Not reported</td><td>11.0 +/-10.5 [0.03,55.2]</td></tr><tr><td>Total</td><td>511</td><td>473/498 (95.0%)</td><td>278/288 (96.5%)</td><td></td></tr></table> These data have been summarized in Genesis User's Guide.
v. Other labeling items: A. A detailed summary of pertinent non-clinical testing information: EMC, mechanical, electrical, and sterilization of device and components;	EMC: The Genesis System User Manual includes a summary of Electromagnetic Compatibility (EMC) testing under the section titled "Electromagnetic Compatibility Information". Electrical: In EMC section – Immunity (include ESD, etc.) Mechanical: Non-clinical performance testing of compatible catheters is included and summarized in the Genesis User's Guide Sterilization: The Genesis System is not provided in sterile form nor is it required to be sterilized prior to use, therefore, sterilization information is not applicable.
B. A detailed summary of the device technical parameters; and	The Genesis system generates a directional 0.08T or 0.1T magnetic field within the patient's heart. The navigation volume is 6 inches in diameter centered at X-ray isocenter.
C. An expiration date/shelf life and storage conditions for the sterile accessories; and	The Genesis System is not provided in sterile form nor is it required to be sterilized prior to use, therefore, expiration date, shelf life, and storage conditions are not applicable.
vi. When available, and according to the timeframe included in the PMS protocol agreed upon with FDA, provide a detailed summary of the PMS data including: A. Updates to the labeling to accurately reflect outcomes or necessary modifications based upon data collected during the PMS experience, and B. Inclusion of results and adverse events associated with utilization of the device during the PMS.	Relevant warnings based on complaints and clinical studies have been included in The Genesis User's Guide.

Date 510 (k) Summary revised: March 4, 2020