June 17, 2021

NaviNetics, Inc
Patrick Gora
V.P. Regulatory Affairs and Quality
206 S Broadway, Suite 700
Rochester, Minnesota 55904

Re: K210700
Trade/Device Name: NaviNetics D1 Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 17, 2021
Received: May 18, 2021

Dear Patrick Gora:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210700

Device Name
NaviNetics D1 Stereotactic System

Indications for Use *(Describe)*
The Intended Purpose of the NaviNetics D1 Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.

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.

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NaviNetics D1 Stereotactic System
510(k) Summary

Date Prepared: June 17, 2021

Submitter's Name / Contact Person

Manufacturer	Contact Person
NaviNetics, Inc. 206 South Broadway, Suite 700 Rochester, MN 55904 Tel 507.361.3570	Patrick Gora VP Regulatory Affairs and Quality gora.patrick@navinetics.com 507.361.3570

General Information

Device Trade Name	NaviNetics D1 Stereotactic System
Common / Usual Name	Stereotaxic Instrument
Classification Name **Product Code** **Predicate Device(s)**	Stereotaxic Instrument, 21 CFR 882.4560 Class II HAW K190887 – Leksell® Vantage™ Stereotactic System (clearance August 1, 2019)

Device Description

The NaviNetics D1 Stereotactic System is a device used for minimally invasive neurosurgical procedures. During image acquisition and treatment, the system's Skull Anchor Key ("Key") achieves reduced weight and patient invasiveness versus common stereotactic head frames that travel extensively around the patient's head and are restrictive to the airway access when positioned.

The system consists of a Key that is affixed to the patient's skull with three titanium stand-off pins and four self-tapping bone anchor screws. The Key serves as the common attachment platform for the D1 Stereotactic Positioner and MRI and CT localizers. The system is based on established stereotactic center-of-arc principles with compatible interventional instruments. These instruments rely on the active working length of 150 mm (arc radius) with stops and guide holders to ensure proper trajectory angle to the brain target. The two degrees of freedom of the arc-quadrant, the Arc and Collar angles, can be manipulated allowing the device to approach the target from a multitude of directions. Linear adjustments can move the arc-quadrant, medial/lateral (X), anterior/posterior (Y), and superior/inferior (Z) to bring the focus to the surgical target. The output of the third-party planning software provides the values of the target coordinates (X_T, Y_T, Z_T) and the surgical trajectory (C_T, A_T) which dictate the settings of the D1 stereotactic device.

Intended Use

The Intended Purpose of the NaviNetics D1 Stereotactic System is target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.

Summary of Technological Characteristics Compared to Predicate

The NaviNetics D1 Stereotactic System has equivalent technological characteristics as its predicate device, Leksell® Vantage™ Stereotactic System. It utilizes the same coordinate system and center-of-arc principle which allows guidance of compatible interventional instruments at any trajectory angle to the brain target.

Substantial Equivalence

The NaviNetics D1 Stereotactic System has equivalent technology, features, and characteristics as the predicate device, K190887, the Leksell® Vantage™ Stereotactic System. The table below provides a comparison of technological characteristics between the NaviNetics D1 Stereotactic System (subject device) and the Leksell® Vantage™ Stereotactic System (predicate device).

	Subject Device	**Predicate Device**
Device Name	NaviNetics D1 Stereotactic System	K190887 Leksell® Vantage™ Stereotactic System
Regulation Number	21 CFR 882.4560	21 CFR 882.4560
Product Code	HAW	HAW
Product Class	II	II
Indications for use	The Intended Purpose of the NaviNetics D1 Stereotactic System is intended to be used for target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example; deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.	The Intended Purpose of Leksell® Vantage™ Stereotactic System is intended to be used for target localization and fixation of the patient head in a coordinate system in order to perform stereotactic neurosurgical procedures, for example, deep brain stimulation, lesioning, biopsies, targeted injections, aspirations and minimal invasive tumor treatments.
Description	The NaviNetics D1 Stereotactic System is included in the arc centered category of stereotactic frames which provide an arc quadrant and a 3D slide to move the arc quadrant about the head. A minimally intrusive Skull Anchor Key attaches to the patient's skull with the use of four (4) skull anchor screws. used to affix the arc centered device to the skull of the patient. The D1 Stereotactic device mounts to the Skull Anchor Key allowing it to pinpoint intracranial targets and guide neurosurgical instruments to these brain targets.	The Leksell® Vantage™ Stereotactic System is a device used for minimally invasive neurosurgical procedures. It enables coordinate referencing and fixation of the patient's skull and brain during image acquisition and treatment. The coordinate referencing enables target localization and accurate stereotactic treatment of brain targets. The system consists of a head frame that is fixated to the patient skull by minimally invasive disposable fixation pins and a number of accessories for frame application and imaging as well as a stereotactic arc and

	Subject Device	Predicate Device
		operating room accessories for the sterile surgical procedure.
Coordinate System	NaviNetics Coordinate System using Cartesian coordinates. The X axis runs left/right, the Y axis runs anterior/posterior and the Z axis runs inferior posterior. The origin of the coordinate system is located to the right, posteriorly, and superiorly to the patient's head. The center of the work envelope, located near the center of the cranial cavity, has a coordinate of (100,100,100)	Leksell Coordinate System using Cartesian coordinates. The X axis runs left/right, the Y axis runs anterior/posterior and the Z axis runs inferior posterior. The origin of the coordinate system is located to the right, posteriorly, and superiorly to the patient's head. The center of the work envelope, located near the center of the cranial cavity, has a coordinate of (100,100,100)
Fixation	Minimally intrusive Skull Anchor Key with three fixation pins and four self-tapping screws.	Head frame attached to patient skull with four fixation pins driven into the outer table of the skull.
Fixation Pins/Screws	Single use titanium pins and self-tapping titanium screws that secure the minimally intrusive Skull Anchor Key to the patient skull.	Single use fixation pins and inserts that secure the Vantage head frame to the patient skull using Leksell Vantage keys.
Principles of Use	The NaviNetics D1 Stereotactic System uses arc center stereotactic principle in which the two angular degrees of freedom rotate orthogonally to each other about a single point called the "focus. A 3D slide alters the position of the focus within the brain. The D1 System has an arc radius of 150mm. This is 40mm less that the predicate which helps reduce the mechanical error by reducing the length of instruments being projected from the arc. The D1 Skull Anchor Key immobilizes the patient within the stereotactic coordinate system called the work envelope. The Skull Anchor Key provides the common attachment site for all components of the D1 System. ● comprises a Skull Anchor key, a 3D slide, and arc ● is target centered ● defines the surgical targets as Cartesian (x,y,z) coordinates within the work envelope of the system	Leksell® Vantage™ Stereotactic System is Center of the arc principle stereotactic device in which the two angular degrees of freedom rotate orthogonally to each other about a single point called the "focus. The working radius of the arc is 190mm. The head frame of the Leksell system immobilizes the patient within the stereotactic coordinate system called the work envelope. The headframe provides the common attachment site for all components of the Leksell system. Cartesian coordinates applied to the brain of the patient by the use of a head frame fixated to the skull. ● comprises a headframe, a 3D slide and arc ● is target centered ● defines the surgical targets as Cartesian (x,y,z) coordinates within the work envelope of the system ● utilizes fiducial markers on CT and/or MRI images to locate the

	Subject Device	Predicate Device
	● utilizes fiducial markers on CT and/or MRI images to locate the images within the stereotactic coordinate system. ● provides support and accessories for surgical instruments to the target	images within the stereotactic coordinate system. ● provides support and accessories for surgical instruments to the target
Materials	Invasive components: Titanium	Invasive components: PEEK with Aluminum tip
	Skull Anchor Key: Delrin® Arc: Aluminum	Head Frame: Glass fiber reinforced Epoxy Arc: Aluminum
Accuracy	0.9mm (mechanical)	0.9mm (mechanical)
Accessories	Neurosurgical instruments designed for a 150 mm working length	Neurosurgical instruments designed for a 190 mm working length

Summary of Non-Clinical Performance Data

Test	Method/Summary	Results
Accuracy	● Mechanical: assembly to position known stereotactic test points at the focus of the arc-quadrant ● Systemic Image: Accuracy of selecting an image target on CT or MRI and positioning the selected point at the focus of the arc-quadrant ● Systemic Surgical: Accuracy of placing a DBS lead, including implantation technique, as verified by post-implant CT scan ● Handling and process step accuracy (e.g., repeated mounting of parts to each other and scale setting accuracy) during mechanical and repeatability accuracy testing Skull anchor key design renders displacement due to head weight as inconsequential	All test cases were shown acceptable for expected outcome. Overall system accuracy is equivalent to the predicate device.

Test	Method/Summary	Results
MR Safety Testing	The device was subjected to and complies with all FDA guidance for MR environment safety and compatibility, including the following safety standards: ● ASTM F2052 ● ASTM F2119 ● ASTM F2182 ● ASTM F2213 ● ASTM F2503	Substantial equivalence to the predicate device is demonstrated through passing results to FDA guidance and these consensus standards.
Cleaning- reusable parts	Validated for manual cleaning and cleaning with a washer-disinfector Manual and washer/disinfector cleaning methods were validated using instructions in the IFU using artificial blood	Parts passed final validation and met all pre-determined acceptance criteria while demonstrating predicate device substantial evidence.
Sterilization- reusable parts	Performed on the subject device, reusable parts were validated for steam sterilization. The validation was used to show the device can obtain a sterility assurance level (SAL) of at least 10^{-6} when steam sterilized at 132°C (270°F) for 4 minutes	Parts passed final validation and met all pre-determined acceptance criteria while demonstrating predicate device substantial evidence.
Biocompatibility	Patient-contacting materials were evaluated for biocompatibility to the following tests: ISO10993-1, ISO10993-5, ISO10993-10 and ISO10993-11	Parts passed final validation and met all pre-determined acceptance criteria while demonstrating predicate device substantial evidence.

Summary of Clinical Performance Data

Based on product classification and predicate devices, clinical testing is not required to demonstrate substantial equivalence.

Conclusion

The performance testing presented demonstrates the NaviNetics D1 Stereotactic System is substantially equivalent with the predicate device, the Leksell® Vantage™ Stereotactic System cleared under K190887.