July 14, 2023

NaviNetics, Inc.
Danielle Jondal
Regulatory Affairs and Quality Specialist
206 S Broadway, Suite 700
Rochester, Minnesota 55904

Re: K231392
Trade/Device Name: NaviNetics Reusable Stereotactic System (NN1000)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: May 9, 2023
Received: May 12, 2023

Dear Danielle Jondal:

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 -S
Digitally signed by Adam D. Pierce -S
Date: 2023.07.14 15:20:26 -04'00'

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)*
K231392

Device Name
NaviNetics Reusable Stereotactic System (NN1000)

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.

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

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510(k) Summary

Prepared on: 2023-05-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NaviNetics Inc.
Applicant Address	206 S Broadway STE 700 Rochester MN 55904 United States
Applicant Contact Telephone	5073613576
Applicant Contact	Ms. Danielle Jondal
Applicant Contact Email	jondal.danielle@navinetics.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NaviNetics Reusable Stereotactic System (NN1000)
Common Name	Stereotaxic instrument
Classification Name	Neurological Stereotaxic Instrument
Regulation Number	882.4560
Product Code	HAW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210700	NaviNetics D1 Stereotactic System	HAW

Device Description Summary

21 CFR 807.92(a)(4)

The NaviNetics Reusable 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 bone anchor screws. The Key serves as the common attachment platform for the 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 surgical planning software provides the values of the target coordinates (X, Y, Z) and the surgical trajectory (CT, AT) which dictate the settings of the stereotactic device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

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.

Technological Comparison

21 CFR 807.92(a)(6)

There are no technological differences in design, material, chemical composition, operation principle or energy source as shown on the Substantial Equivalence table from the predicate to the subject device, with one minor exception that does not affect device performance, accuracy or effectiveness. The previous working X, Y, and Z axis of 100, 100, 100 is now slightly adjusted to 100, 105, 96.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The performance testing presented demonstrates the design changes to the NaviNetics Resusable (D1) Stereotactic System are substantially equivalent to the predicate and original device, K210700.