February 5, 2025

ClaroNav
Karen Wu
Director of Regulatory Affairs
1140 Sheppard Avenue West Unit 10
Toronto, ON M3K2A2
Canada

Re: K241327
Trade/Device Name: Navient Image Guide Navigation System (955-NC-NC)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 3, 2025
Received: January 6, 2025

Dear Karen Wu:

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2025.02.05 16:57:21 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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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)*
K241327

Device Name
Navient Image Guided Navigation System, Cranial

Indications for Use *(Describe)*
Navient is a computerized surgical navigation system intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.
The Navient system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT, MR based model of the anatomy.
Indications:
Example procedures include but are not limited to:
Cranial Procedures:
• Tumor resections
• Cranial biopsies
• Craniotomies
• Pediatric Catheter Shunt Placement
• General Catheter Shunt Placement

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.

510(K) SUMMARY
NAVIENT IMAGE GUIDED NAVIGATION SYSTEM

Sponsor:	ClaroNav 1140 Sheppard Avenue West, Unit 10 Toronto, Ontario, M3K 2A2 Canada
Contact Person	Karen Wu Director of Regulatory Affairs
Phone	+1 647 552 1489
e-mail	ra@claronav.com

Date	February 5, 2025
Device Proprietary Name	Navient Image Guided Navigation System, Cranial
Common Name	Navient
Product Code	HAW
Class	Class II
Regulation Number	21 CFR 882.4560
Regulation Name	Stereotaxic instrument
Classification Panel	Neurology

Predicate Devices
Primary predicate: StealthStation S8 Cranial (K212397)

Indications for Use

Navient is a computerized surgical navigation system intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.

The Navient system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT, MR based model of the anatomy.

Indications:

Example procedures include but are not limited to:
Cranial Procedures:

- Tumor resections
- Cranial biopsies
- Craniotomies
- Pediatric Catheter Shunt Placement
- General Catheter Shunt Placement

Technological Characteristics

Navient is an image guided navigational system intended to assist with preoperative planning and real-time positioning of surgical tools during stereotaxic procedures via (infrared) tracking technology. The system is essentially composed of a computerized main unit (computer), a Navient IR CameraBox, Navient cart, Navient navigation software, and corresponding accessory sets intended for specific clinical applications.

Navient's guidance function is based on the patient images acquired prior to the procedure, combined with optical measurements of the pose of navigated instruments relative to the patient's anatomy. To enable navigation, the reference instrument/accessory is attached to the patient to enable tracking of the patient's anatomy. The patient images are then spatially registered with the patient's anatomy by matching landmark locations marked on both the image and the patient, followed by matching a path traced by the user on the patient's anatomy with a model of patient's anatomical surface automatically generated from the image data.

Depending on the desired clinical application, the Navient system also includes the following instrument/accessory kits. These reusable instruments are intended to be sterilized/disinfected prior to use.

- Cranial Accessory Kit (955-NC-AKC)
- Biopsy Accessory Kit (955-NC-AKB)

Disposable tracker instruments are also available based on user preference.

Navient Software Workflow:

Navient software operation proceeds sequentially through 5 stages:

1. Images: Load the CT or MR images, review and explore images and perform image fusion.
2. Planning: The planning stage, depending on the procedure types
3. Set Up: attach the Patient reference, adjust the tracking system position and verify the instruments' tip calibration accuracy.
4. Registration: Using Registrator, point to the marked landmarks on the actual patient's skin, then trace a path on the patient's face to refine the registration.
5. Navigation: Navigate the position of the tip of various instruments in the image volume.

Performance Data

Navient's performance testing included:

- **Reprocessing validation:**

Reprocessing instructions are available in the user manual. Navient instrument (worst case) was validated for manual and automated cleaning in accordance with AAMI TIR 30: 2011(R) 2016, and steam sterilization in accordance with ANSI/AAMI/ISO 17665-1:2006/(R)2013 for (SAL) of ≤10-6.

- **Biocompatibility Testing:**

Patient contacting instrument (worst case) was validation for biocompatibility based on the identified endpoints for product with limited intact skin or mucosal membrane contact and contact tissue/bone/dentin: cytotoxicity, sensitization and irritation, material mediated pyrogenicity and acute systemic toxicity. Results indicate the body-contacting Navient instruments do not introduce any toxic or biologically harmful reactions and are therefore safe to be used for body-contacting applications when used as intended.

- **Software:**

In accordance with FDA Guidance: Content of Premarket Submissions for Device Software Functions (June 14, 2023), the documentation level selected for the submission was *Enhanced Documentation*.

- **Electrical Safety and Electromagnetic Compatibility (EMC):**

Comprehensive performance testing has been conducted on the Navient device in accordance with IEC 60601- 1 and IEC 60601-1-2.

- **Full system accuracy bench testing (overall accuracy):**

Navient has been validated to a mean positional error of ≤ 2.0 mm and a mean angular error of ≤ 2.0deg. Table below summarizes the full system accuracy test of Navient cranial module. This performance was determined using representative phantoms with system components that are deemed the worst-case in the Navient clinical applications.

Full System Accuracy (Navient Cranial Module)	**Positional Error (mm)**			**Angular Error (degree)**		
	Mean	**Standard Deviation**	**99% Confidence Interval**	**Mean**	**Standard Deviation**	**99% Confidence Interval**
	1.36mm	0.66mm	2.89mm	1.01 deg	0.40 deg	1.95deg

- **Accuracy test when exchanging cranial reference frame**

As part of the Navient cranial workflow, the user is expected to perform registration with cranial reference frame 950-NC-CRF-A (in non-sterile environment) and then remove it and place cranial reference frame 950-NC-CRF-B (which is sterile) after the patient is draped. The accuracy requirement regarding the exchange of the cranial reference frames has been validated with a distance/movement of less than 1mm. The validation was performed on a representative phantom with the Navient system.

- **Human factors/usability:**

Usability/human factor evaluation was performed in accordance with IEC 62366-1:2015+AMD1:2020.

Substantial Equivalence:

The subject Navient system is substantially equivalent to the predicate devices StealthStation S8 Cranial (K212397). Navient system and StealthStation S8 have the same intended use and similar technological characteristics, but Navient does not raise new safety/effectiveness questions and was tested in non-clinical studies in accordance with an appropriate methodology.
A comparison of the subject Navient system and the predicate device is presented in Table 1 below:

Table 1. Comparison of Indications for use and Technological Characteristics

Feature/ Characteristic	**Subject Device** **Navient System (955-NC-NC) – cranial (including biopsy) application**	**Predicate** **StealthStation S8 (Cranial)**	**Justification of difference**
<u>Intended Use</u>			
Class/Product Code/Classification Name	Regulation Number: 21 CFR 882.4560 Regulation Name: Stereotaxic Instrument Regulatory Class: Class II	K212397 Regulation Number: 21 CFR 882.4560 Regulation Name: Stereotaxic Instrument Regulatory Class: Class II	Identical classification and applicable regulation number.
Intended Use	Navient is a computerized surgical navigation system intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.	The StealthStation™ S8 System is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures.	Subject Navient has the same general intended use as the predicate device and: "as an aid for precisely locating anatomical

Feature/ Characteristic	Subject Device Navient System (955-NC-NC) – cranial (including biopsy) application	Predicate StealthStation S8 (Cranial)	Justification of difference
			structures in either open or percutaneous neurosurgical procedures."
Indications for Use	The Navient system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT, MR based model of the anatomy. Example procedures include but are not limited to: Cranial Procedures: • Tumor resections • Cranial biopsies • Craniotomies	It is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Tumor resections • General ventricular catheter placement	Similar. Although the example cranial procedures listed may slightly differ, both the subject device and predicate device specify <u>any medical condition in which the used of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure can be identified relative to images of the anatomy</u>.

Feature/ Characteristic	**Subject Device** **Navient System (955-NC-NC) – cranial (including biopsy) application**	**Predicate** **StealthStation S8 (Cranial)**	**Justification of difference**
	• Pediatric Catheter Shunt Placement • General Catheter Shunt Placement	• Pediatric ventricular catheter placement • Depth electrode, lead, and probe placement • Cranial biopsies	
Use Environment	Surgical setting	Surgical setting	Identical
Target Population	Patients for whom stereotactic image guided surgery is appropriate	Patients for whom stereotactic image guided surgery is appropriate	Identical
Users	Medical practitioner	Medical practitioner	Identical
Technological Characteristics			
Operating Principles	Surgical navigation system with optical (infrared) tracking technology	Surgical navigation system with optical (infrared) and EM tracking technology	Identical optical tracking. Navient does not support EM tracking.
Input imaging modality	CT and MR	X-ray, MR, and nuclear medicine	Subject Navient supports a subset of the predicate's

Feature/ Characteristic	**Subject Device** **Navient System (955-NC-NC) – cranial (including biopsy) application**	**Predicate** **StealthStation S8 (Cranial)**	**Justification of difference**
			inputs MR and CT (which is x-rays based imaging).
Dynamic object pose measurement technology	Stereoscopic Optical Tracking system	Stereoscopic Optical Tracking System and EM tracking technology	Identical optical tracking. Navient does not support EM tracking.
Localization Technology/Illumination of tracking targets	Optical (infra-red)	Optical (infra-red)/ electromagnetic tracking	Identical infra-red technology. Navient does not support EM tracking.
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM	Network Connectivity CD, DVD, USB DICOM	Identical
General Device Components	Platform/cart, software, surgical and reference instruments	Platform/carts (2), software, surgical and reference instruments	Subject Navient requires 1 cart to support the optical tracking system while the predicate device requires a

Feature/ Characteristic	**Subject Device** **Navient System (955-NC-NC) – cranial (including biopsy) application**	**Predicate** **StealthStation S8 (Cranial)**	**Justification of difference**
			main cart and 1 camera cart.
Localization Referencing	Camera for optical tracking	Camera for optical tracking or an emitter and instrument interface for electromagnetic tracking	Subject Navient supports a subset of the predicate's referencing functionality (optical tracking).
Compatible Instruments	Instruments for optical localization/tracking, including: • Patient tracker • Pointer/registrators • Optical trackers • Reference frames • Adapters • Calibrating instruments	Instruments for optical and electromagnetic (EM) localization/tracking, including: • Patient tracker • Pointer/registrators • Optical trackers • Reference frames • Adapters • Calibrating instruments • Dilating balloon • Blades • Suction tip	Subject Navient supports optical tracking but does not support EM tracking. Within the optical tracking instruments, subject Navient system supports a subset of the predicate's instrumentation.

Feature/ Characteristic	**Subject Device** **Navient System (955-NC-NC) – cranial (including biopsy) application**	**Predicate** **StealthStation S8 (Cranial)**	**Justification of difference**
Patient to CT image registration	Landmark based registration followed by surface matching	Landmark based registration followed by surface matching	Identical
Performance Characteristics			
Performance Accuracy	≤2.0mm, ≤2° mean error	≤2.0mm, ≤2° mean error	Identical
3D Image	Support 3D Registration and Navigation	Support 3D Registration and Navigation	Identical

Conclusions

Navient system has been shown through testing and technical comparison to be substantially equivalent to the identified predicate and referenced devices when used as intended.