June 20, 2025

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

Re: K243053
Trade/Device Name: Navient Image Guided Navigation System (ENT)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: May 22, 2025
Received: May 22, 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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K243053

Device Name
Navient Image Guided Navigation System (ENT)

Indications for Use *(Describe)*
Navient Image Guided Navigation System (ENT):
Navient is a computerized surgical navigation system intended as an aid for precisely locating anatomical structures. 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 anatomy model.
Indications:
Example procedures include but are not limited to:
ENT Procedures:
• Transsphenoidal procedures
• Maxillary antrostomies
• Ethmoidectomies
• sphenoidotomies
• Sphenoid explorations
• Turbinate resections
• Frontal sinusotomies
• Intranasal procedures
• Intranasal tumor resections
• All ENT related skull base surgery

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
NAVIENT IMAGE GUIDED NAVIGATION SYSTEM (ENT)

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 Prepared	June 20, 2025
Device Proprietary Name	Navient Image Guided Navigation System (ENT)
Common Name	Navient
Product Code	PGW
Class	Class II
Regulation Number	21 CFR 882.4560
Regulation Name	Stereotaxic instrument
Classification Panel	Ear Nose & Throat

Predicate Devices
Primary predicate:

NaviENT System (K163439)

Indications for Use

Navient is a computerized surgical navigation system intended as an aid for precisely locating anatomical structures. 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 anatomy model.

Indications:

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

- Transsphenoidal procedures
- Maxillary antrostomies
- Ethmoidectomies
- sphenoidotomies
- Sphenoid explorations
- Turbinate resections
- Frontal sinusotomies
- Intranasal procedures
- Intranasal tumor resections
- All ENT related skull base surgery

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 optical 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 set.

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.

- ENT Accessory Kit (955-NE-ACCK)*

**a second set of the ENT Accessory Kit, called Set B, is included in the Navient system. Set B allows use of navigation on back-to-back OR cases without having to wait for sterilization of the main set. Set B part numbers are similar to the main set, except it is affixed with "-B". It is also marked with a different serial number.*

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
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 $\leq 10^{-6}$.

- **Biocompatibility Testing:**

Patient contacting instrument (worst case) was validation for biocompatibility based on the identified endpoints for product with limited (less than 24 hours) breached or compromised surface contact: cytotoxicity, sensitization, 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:**

Navient has been validated to the positional accuracy of ≤ 2.0 mm (mean=1.52 mm, STD=0.93 mm, 99% confidence interval of 3.68 mm), with the angular error of ≤ 2.0 deg (mean=1.13 deg, STD=0.43 deg, 99% confidence interval of 2.13 deg). This performance was determined using representative phantoms with system components that are deemed the worst-case in the Navient clinical applications.

- **Human factors/usability:**

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

Substantial Equivalence:

The subject Navient system (Model 955-NC-NC) is substantially equivalent to the predicate device NaviENT system, model 955-NE-NE, which is the previous generation of the subject device. The predicate was previously cleared under K163439.

Both subject and predicate devices are essentially composed of a computerized main unit (computer), a Navient IR CameraBox, Navient cart, Navient navigation software, and corresponding accessory set. Both are intended for ENT applications/procedures. A comparison of subject Navient system and the predicate NaviENT system 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)**	**Predicate Device** **NaviENT System (955-NE-NE)**	**Justification of difference**
Class/Product Code/Classification Name	Regulation Number: 21 CFR 882.4560 Regulation Name: Stereotaxic Instrument Regulatory Class: Class II	K163439 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.	Navient is a computerized surgical navigation system intended as an aid for precisely locating anatomical structures.	Identical. The subject Navient system and the predicate NaviENT system are intended to be used clinically as surgical navigation systems.
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.	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.	Identical. The subject Navient system and the predicate NaviENT system have the same indications for use.

Feature/ Characteristic	Subject Device Navient System (955-NC-NC)	Predicate Device NaviENT System (955-NE-NE)	Justification of difference
	Example procedures include but are not limited to: • Transsphenoidal procedures • Maxillary antrostomies • Ethmoidectomies • Sphenoidotomies • Sphenoid explorations • Turbinate resections • Frontal sinusotomies • Intranasal procedures • Intranasal tumor resections • All ENT related skull base surgery	Example procedures include but are not limited to: • Transphenoidal procedures • Maxillary antrostomnies • Ethmoidectomies • Sphenoidectomies • Sphenoid explorations • Turbinate resections • Frontal sinusotomnies • Intranasal procedures • Intranasal tumor resections • All ENT related skull base surgery	
Use Environment	Surgical setting	Surgical setting	Identical
Target Population	Patients for whom stereotactic image-guided surgery (ENT) is appropriate	Patients for whom stereotactic image-guided surgery (ENT) is appropriate	Identical
Users	Medical practitioners (ENT Surgeons, i.e. Otolaryngologist)	Medical practitioners (ENT Surgeons, i.e. Otolaryngologist)	Identical
Operating Principles	Surgical navigation system with optical tracking technology	Surgical navigation system with optical tracking technology	Identical
Input imaging modality	CT and MR	CT and MR	Identical
Dynamic object pose	Stereoscopic Optical Tracking	Stereoscopic Optical Tracking	Identical

Feature/ Characteristic	Subject Device Navient System (955-NC-NC)	Predicate Device NaviENT System (955-NE-NE)	Justification of difference
measurement technology	system	system	
Localization Technology/Illumination of tracking targets	Optical	Optical	Identical
Scanner Interface Technology (to imaging devices)	Network Connectivity CD, DVD, USB DICOM	Network Connectivity CD, DVD, USB DICOM	Identical
General Device Components	Require a platform/cart, software, surgical and reference instruments	Require a platform/cart, software, surgical and reference instruments	In general, both subject Navient system and predicate NaviENT system require a platform/cart, software, surgical and reference instruments.
Platform/Cart	Platform/cart: - Computer unit (All-in-one PC [AIO]) - Navient Camera for optical tracking - Cart: o Lightweight 30kg o 40 (W) x 50 (D) x 135 (H) cm (when	Platform/cart: - Computer unit (MacBook Laptop) - Navient Camera for optical tracking - Cart with laptop stand: o Lightweight 26kg o 40 (W) x 45 (D) x 100 (H) cm (when	Platform/cart: - Computer: o Subject system utilizes an All-in-one PC (AIO) with touch screen monitor o Predicate system utilizes a MacBook Laptop - Camera: Navient camera is identical for the subject and predicate systems.

Feature/ Characteristic	Subject Device Navient System (955-NC-NC)	Predicate Device NaviENT System (955-NE-NE)	Justification of difference
	extended: 190 (H) cm) o Omni directional front wheels	extended: 160 (H) cm) o Omni directional front wheels	- Cart: subject and predicate devices utilize similar adjustable-height carts, which must hold the computer unit and the camera. o Predicate cart: ▪ Includes a laptop holder and holds the camera around the mid-section of the cart. o Subject cart: ▪ All-in-one PC (AIO) is directly attached to the cart, and the camera is placed at the top of the cart.
Software	Software: - Navient software with the following workflow: 1. Images: Load the CT or MR images, review and explore images, and perform image fusion. 2. Planning	Software: - Navient software with the following workflow: 1. Images: Load the CT or MR images, review and explore images, and perform image fusion. 2. Planning	Software: Identical Navient software and workflow

Feature/ Characteristic	Subject Device Navient System (955-NC-NC)	Predicate Device NaviENT System (955-NE-NE)	Justification of difference
	○ Landmarks: Mark easily identifiable anatomical landmarks on the patient scan. ○ Segmentation: Generate a 3D model of the tumor or sinus. 3. Set Up: attach the Patient reference, adjust the tracking system position, and verify the instruments' tip calibration accuracy. 4. Registration: Using the Registration Probe, point to the marked landmarks on the actual patient's skin, then trace a path on the patient's face to refine the registration.	○ Landmarks: Mark easily identifiable anatomical landmarks on the patient scan. ○ Segmentation: Generate a 3D model of the tumor or sinus. 3. Set Up: attach the Patient reference, adjust the tracking system position, and verify the instruments' tip calibration accuracy. 4. Registration: Using the Registration Probe, point to the marked landmarks on the actual patient's skin, then trace a path on the patient's face to refine the registration.	

Feature/ Characteristic	Subject Device Navient System (955-NC-NC)	Predicate Device NaviENT System (955-NE-NE)	Justification of difference
	5. Navigation: Navigate the position of the tip of various instruments in the image volume.	5. Navigation: Navigate the position of the tip of various instruments in the image volume.	
Instrumentation	Surgical reference instruments for optical localization/tracking: - Patient Tracker (2 sets) (950-NE-PT) - Maxillary Seeker (950-NE-MS) - Frontal Seeker (950-NE-FS) - Bayonet Probe (950-NE-BP) - Registration Probe (950-NE-RP) - Tip Calibrator (950-NE-TC) - Universal Tracker (2 sets) (950-NE-UT1, 950-NE-UT2) - Four C-Clamps (950-NE-UTCS, 950-NE-UTCM, 950-NE-UTCL, 950-NE-UTCXL) Note: instruments are to be steam sterilized by the user prior to use in the ENT Sterilization Tray (950-NE-STE)	Surgical reference instruments for optical localization/tracking: - Patient Tracker (2 sets) (950-NE-PT) - Maxillary Seeker (950-NE-MS) - Frontal Seeker (950-NE-FS) - Bayonet Probe (950-NE-BP) - Registration Probe (950-NE-RP) - Tip Calibrator (950-NE-TC) - Universal Tracker (2 sets) (950-NE-UT1, 950-NE-UT2) - Four C-Clamps (950-NE-UTCS, 950-NE-UTCM, 950-NE-UTCL, 950-NE-UTCXL) Note: instruments are to be steam sterilized by the user prior to use in the ENT Sterilization Tray (950-NE-STE)	Surgical reference instruments for optical localization/tracking: - Identical instrumentation

Feature/ Characteristic	**Subject Device** **Navient System (955-NC-NC)**	**Predicate Device** **NaviENT System (955-NE-NE)**	**Justification of difference**
Localization Referencing	Camera for optical tracking	Camera for optical tracking	Identical
Patient to CT image registration	Landmark based registration followed by surface matching	Landmark based registration followed by surface matching	Identical
Performance Accuracy	Accuracy with ≤2.0mm error	Accuracy with ≤2.0mm 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 device when used as intended.