DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 1, 2017

Claronav Inc.
Ahmad Kolahi
CEO
1140 Sheppard Avenue West - Unit 10
Toronto, M3K 2A2 CA

Re: K163439
Trade/Device Name: Navient
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: August 2, 2017
Received: August 3, 2017

Dear Ahmad Kolahi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

NaviENT

Indications for Use *(Describe)*

NaviENT is a computerized surgical navigation system intended to guide sinus and trans-nasal skull base endoscopic surgery by dynamically presenting the location of the tip of a surgical instrument mapped to a corresponding location in a pre-acquired CT scan of the patient's head. The device is intended for use by a qualified ENT surgeon (otolaryngologist).

NaviENT 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. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomnies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomnies, intranasal procedures, intranasal tumor resections, and 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.

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510(k) SUMMARY

SUBMITTER INFORMATION

Company Name:	ClaroNav Kolahi Inc.
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Company Phone:	(647) 951-1525
Company Fax:	(647) 951-1524
Contact Person:	Ahmad Kolahi, CEO
Date Summary Prepare:	August 2nd 2017

DEVICE IDENTIFICATION

Trade/Proprietary Name:	NaviENT
Classification:	II
Generic Device Name:	Surgical Navigation System
Product Code:	PGW
Classification Names:	Stereotaxic Instrument
Classification Regulation #:	21 CFR 882.4560
Classification Panel:	ENT
Predicate Device:	Karl Storz Navigation Panel Unit (NPU) System (K122096)

DEVICE DESCRIPTION

NaviENT is a cart-based, computerized, image-guided navigational system, operating as a combined package for performing guided ENT surgery.

Using pre-acquired CT scan of the sinus, NaviENT provides the surgeon (usually otolaryngologists) with easy-to-use real-time guidance during sinus surgery. The key function performed by NaviENT during navigation is visualization of the instrument tip relative to the surrounding anatomy. This visualization assists the surgeon in performing the surgery.

NaviENT consists of four main components:

1. NaviENT Cart: Its main purpose is to hold the laptop computer and the tracking camera. The cart is light weight and the arm height can be adjusted. This allows the user to easily position the system in the operating room.
2. Tracking System: It contains a stereoscopic camera and an IR LED light source, both operating in the near infrared (NIR) light spectrum. The tacking system identifies and pin-points checkered marker patterns affixed on the NaviENT instruments.
3. Laptop Computer: The NaviENT software runs on a 15.4" Apple Mac Book Pro laptop. Windows 10 operating system is installed on the laptop. The tracking camera's live video stream is received by the laptop via a thunderbolt port and is processed by the NaviENT application.
4. NaviENT Instruments: The instruments are marked with Black & White patterns which make them trackable by the NaviENT Tracking system. It includes 950-NE-PT Patient Tracker, 950-NE-RP Registration Pointer, 950-NE-FS Frontal Seeker, 950-NE-MS Maxillary Seeker, 950-NE-BP Bayonet Probe, 950-NE-TC Tip Calibrator and 950-NE-UT Universal Tag.

NaviENT Clinical Workflow:

NaviENT Software workflow provides step by step instructions on how to set up and use the system in the Operating room. The software has been pre-installed on the NaviENT laptop. The shortcut for the NaviENT application is placed on the desktop. When started it opens the data browser window, allowing the user to load, import and delete patient image data. Once data is loaded, NaviENT operation proceeds sequentially through 5 stages as follows:

1. Verify: This stage displays the 3D data as well as 2D axial, coronal and sagittal reformatted slice views and allows the user to rotate, zoom and explore the data.
2. Mark Landmarks: This stage walks the user through selecting a few anatomical landmarks on the 3D scan. The names of each landmark and an illustration of its approximate locations are displayed for convenience.
3. Set Up: This stage provides step by step instructions to place the patient tracker and position the tracking device. The live video stream displayed on the side panel makes it very intuitive to position the camera.
4. Registration: NaviENT uses landmark based registration followed by trace based registration. This stage provides step by step instructions to perform registration process.
5. Navigation: Presents real-time location of the instrument tip super imposed on the 2D images of sagittal, axial and coronal views of the patient scan.

ClaroNav Kolahi

INDICATIONS FOR USE

NaviENT has the following Indications for Use:

NaviENT is a computerized surgical navigation system intended to guide sinus and trans-nasal skull base endoscopic surgery by dynamically presenting the location of the tip of a surgical instrument mapped to a corresponding location in a pre-acquired CT scan of the patient's head. The device is intended for use by a qualified ENT surgeon (otolaryngologist).

NaviENT 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. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomnies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomnies, intranasal procedures, intranasal tumor resections, and ENT related skull base surgery.

SUBSTANTIAL EQUIVALENCE

NaviENT shares technological, performance and clinical features and has an identical intended use as the Karl Storz Navigation Panel Unit (NPU) System:

Predicate Company	**Predicate Trade Name**	**510(k) #**	**Predicate Intended Use**
Karl Storz	Karl Storz Navigation Panel Unit (NPU) System	K122096	The Navigation Panel Unit System (NPU) is an intraoperative image guided localization system that links a freehand probe tracked by a passive marker sensor system to a virtual computer image space on a patient's preoperative diagnostic image data set. The system is intended to be used as a positioning aid for navigation in ENT surgery, including but not limited to endoscopic surgery. The NPU is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the radiological imaging-based model of the anatomy. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomnies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomnies, intranasal procedures, intranasal tumor resections, otologic surgery, and ENT skull base surgery.

Comparison of Technological Characteristics

NaviENT shares many clinical, technological and performance characteristics with a predicate device, the Karl Storz Navigation Panel Unit (NPU) System. These characteristics are outlined in the following table:

Feature/ Characteristic	Karl Storz NPU (predicate)	NaviENT	Rationale for any differences
Intended Use			
Class/Product Code/Classification Name	Class II/ HAW/ 882.4560 (Stereotaxic Instrument)	Class II/ PGW/ 882.4560 (Stereotaxic Instrument)	Same
Indications for Use	The Navigation Panel Unit System (NPU) is an intraoperative image guided localization system that links a freehand probe tracked by a passive marker sensor system to a virtual computer image space on a patient's preoperative diagnostic image data set. The system is intended to be used as a positioning aid for navigation in ENT surgery, including but not limited to endoscopic surgery. The NPU is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the radiological imaging-based model of the anatomy. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomnies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomnies, intranasal procedures, intranasal tumor resections, otologic surgery, and ENT skull base surgery.	NaviENT is a computerized surgical navigation system intended to guide sinus and trans-nasal skull base endoscopic surgery by dynamically presenting the location of the tip of a surgical instrument mapped to a corresponding location in a pre-acquired CT scan of the patient's head. The device is intended for use by a qualified ENT surgeon (otolaryngologist). NaviENT 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. Surgery procedures include but are not limited to the following: transphenoidal procedures, maxillary antrostomnies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, frontal sinusotomnies, intranasal procedures, intranasal tumor resections, and ENT related skull base surgery.	Same indications, phrased differently.

Feature/ Characteristic	Karl Storz NPU (predicate)	NaviENT	Rationale for any differences
Main functions	Locating anatomical locations inside patient.	Locating anatomical locations inside patient	Same.
Use Environment	Operating Room	Operating Room	Same.
Target Population	Patients who has to go under endoscopic sinus surgery or ENT skull base surgery.	Patients who has to go under endoscopic sinus surgery or ENT skull base surgery.	Same.
Users	ENT Surgeons(Otolaryngologist)	ENT Surgeons(Otolaryngologist)	Same.
Technological Characteristics			
Input imaging modality	CT and MRI	CT	Navient supports a subset of the predicate's inputs, therefore any input suitable for NaviENT is suitable for the predicate device as well.
Dynamic object pose measurement technology	Stereoscopic Optical Tracking system	Stereoscopic Optical Tracking system	same
Illumination of tracking targets	Infra-red light	Infra-red light	Same.
Patient to CT image registration	Landmark based registration followed by surface matching	Landmark based registration followed by trace based surface matching	Same.

Standard Navigation Instruments	1. Patient Tracker 2. Navigation Probe 3. Frontal Sinus Probe 4. DrillCut-X Shaver Handpiece 5. Microscope Probe 6. Optical Instrument Tracker	1. Patient Tracker 2. Bayonet pointer 3. Frontal Ostium Seeker 4. Universal Tag 5. Registration Pointer 6. Maxillary Ostium Seeker 7. Calibrator	Similar. NaviENT provides extra instruments of Registration Pointer, Maxillary Ostium Seeker and Calibrator. This is intended to improve usability. NaviENT does not require the use of a Microscope Probe and Optical Instrument Tracker.
Mount for camera and display	Both Camera and display mounted on the cart	Both camera and the display mounted on the cart.	Similar. NaviENT cart has foldable arm where as NPU cart is pull up/down bar.
Instruments Tip Calibration	By touching Patient Tracker	By touching Calibrator instrument.	Similar. NaviENT has provided a designated instrument to calibrate instrument tips where as NPU is using patient tracker.
Presentation of navigation guidance	3D graphics presentation of instrument position, angle relative to patient image.	3D graphics presentation of instrument position, angle relative to patient image.	Same.
Software Equivalence			
Clinical Software Features	DICOM image visualization in 3D and 2D views (axial, coronal, sagittal), Patient to image registration features	DICOM image visualization in 3D and 2D views (axial, coronal, sagittal), Patient to image registration features	Similar. Minor differences, mainly in user interface to the same underlying functions.
Performance Characteristics			

System Accuracy	N/A	Average Error less than 2.0	Similar. A direct published accuracy data for the predicate is not available however the predicate to NPU system (i.e. k964229) claims accuracy of 2.56mm.
Materials **Equivalence**			
Patient Mucosal membrane contacting parts	Navigation Probe Frontal Sinus Probe	Bayonet pointer Frontal Ostium Seeker Maxillary Ostium Seeker	Similar. NPU Navigation probe is equivalent to NaviENT Bayonet probe. NaviENT provides both Frontal and Maxillary Ostium seekers. This improves usability.
Patient contacting Instruments Material	Medical grade Stainless Steel	Medical grade Stainless Steel	Same.

Determination of Substantial Equivalence

NaviENT is identical to the predicate device in indications for use, intended target populations, the target users, the principles of operation and the indications for use.

NaviENT has very similar technological characteristics to the predicate device. The supported Tracking device, image modality, registration techniques and software are very similar. Minor technological differences between NaviENT and predicate device include:

- Markers: Both NaviENT and the predicate device are using Optical Tracking system with very similar principle of operation. The only minor difference is that, NPU is using spherical shape marker where as NaviENT is using multi-facet flat markers. This difference does not impact the safety and effectiveness of either device in performing its intended use.
- Instruments: NaviENT provides dedicated instruments to perform the Registration process, while the predicate device uses its Navigation Probe to perform registration process as well. NaviENT provides a dedicated instrument to perform Calibration process, while the predicate device uses its Patient Tracker not only to track the patient but also to perform the Calibration process. NaviENT also provides additional dedicated instrument of Maxillary Ostium Seeker, while the predicate does not provide such an instrument. The dedicated instruments improves the usability. NaviENT does not provide Microscope Probe and Optical Instrument Tracker.

- While the predicate device permits using MRI data and NaviENT does not, equivalence is maintained for all cases where CT data input is used.

The above design differences relate solely to the usability aspects of the devices, not to the core functions they perform, which are substantially identical. These differences do not impact the safety and effectiveness of either device in performing its intended use.

In conclusion, the systems are substantially equivalent.

COMPLIANCE TO STANDARDS AND REGULATIONS

The following FDA approved standards are met by the Navident system as demonstrated through performance testing:

ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices
AAMI/ANSI/IEC 62304:2006 Medical Device Software - Software Life Cycle Processes.
ISO 15223-1 Second Edition 2012-07-01, medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements.
AAMI/ANSI/ISO 10993-1:2009/(R) 2013, Biological Evaluation of Medical Devices - part 1: evaluation and testing within a risk management process.
AAMI / ANSI / ISO 10993-5:2009/(R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity.
AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod)
AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3)
IEC 62471 First edition 2006-07, photobiological safety of lamps and lamp systems. (Radiology)

SUMMARY OF PERFORMANCE TESTING

Safety and performance testing of the NaviENT system was conducted in accordance with all above referenced standards and regulations. All system requirements, including accuracy requirements, were validated thoroughly, and found to be comparable to those specified by the FDA cleared predicate devices.

The following safety and performance testing was conducted:

1. Software Validation: Successful testing verifying the software requirements are met and software performs as intended.
2. Cleaning and Sterilization Validation: A representative sample of the re-usable NaviENT components were tested to validate that the components can withstand the recommended cleaning, disinfection and sterilization processes and that a sterility assurance level (SAL) of 10-6 can be achieved using the recommended sterilization protocols. The sterilization validation testing was conducted according to ISO 17665-1:2006 and it validated that the re-usable NaviENT components can be sterilized to reach an SAL of 10-6.
3. Bench Testing: All planned performance tests were executed as planned, and all of them succeeded in meeting their acceptance criteria. Accuracy testing was conducted to ensure that the NaviENT system met the prescribed requirement for accuracy. The NaviENT system demonstrates performance in 3D positional accuracy with average error of less than 2mm. this performance was determined using 3 different human head models in an OR simulated environment with all of the typical navigation instruments.
4. Electrical and EMC Testing: The NaviENT system was tested for electrical safety and essential performance according to the requirements IEC 60601-1:2005 In addition, NaviENT passed all the relevant requirements of the IEC 60601-1-2:2007 and IEC 62471:2006 standards demonstrating that the device meets the applicable electromagnetic compatibility requirements as well as and that the lights used in the NaviENT system are safe to be used as intended.
5. Biocompatibility Testing: The patient contacting NaviENT components were tested according to the requirements of ISO 10993-1 and were deemed to be biocompatible.
6. Human Factors: NaviENT human factors report and validation testing provided sufficient data to support their conclusion of substantial equivalence with regards to differences in system user interface and use scenarios from the predicate.

CONCLUSION

NaviENT is identical to the predicate device in indications for use, intended target populations, the target users, the principles of operation and the indications for use.

NaviENT has very similar technological characteristics to the predicate device. The supported Tracking device, image modality, registration techniques and software are very similar. The only differences relate to minor differences in the markers used by the tracking devices; the instruments provided and the type of image data input. These differences do not impact the safety and effectiveness of either device in performing its intended use.

In conclusion, NaviENT and its identified predicate systems are substantially equivalent.