June 27, 2022

ClaroNav Inc.
Carly Desmond
Director of Regulatory Affairs
1140 Sheppard Avenue West Unit 10
Toronto, Ontario M3K 2A2
CANADA

Re: K210947
Trade/Device Name: Navident
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: June 2, 2022
Received: June 2, 2022

Dear Carly Desmond:

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,

Andrew I. Steen
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)*
K210947

Device Name
Navident

Indications for Use *(Describe)*

Navident is a computerized dental navigational system intended to assist preoperative planning and to guide drilling in a patient jaw during implantation surgery, using pre-acquired CT scan of the jaw. The device is intended for use by a qualified dental surgeon in the treatment of partially or fully edentulous jaws.

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

K210947
ClaroNav's Navident

Sponsor:	ClaroNav Inc. 1140 Sheppard Avenue West, Unit 10 Toronto, Ontario, M3K 2A2 Canada
Contact Person	Doron Dekel
Phone	+1 647 868 6813
e-mail	doron@claronav.com

Submission Date	June 24, 2022

Device Proprietary Name	Navident
Common Name	Surgical Navigation System
Classification	PLV
Class	II
Regulation	21 CFR 872.4120; Bone Cutting Instrument and Accessories
Classification Panel	Dental

Predicate Devices

Primary predicate: ClaroNav's Navident (K161406)

Reference device: X-Nav's X-Guide (K200662)

Indications for Use

Navident is a computerized dental navigational system intended to assist preoperative planning and to guide drilling in a patient jaw during implantation surgery, using pre-acquired CT scan of the jaw. The device is intended for use by a qualified dental surgeon in the treatment of partially or fully edentulous jaws.

Technological Characteristics

Navident is an image-guided dental navigational system intended to assist with preoperative planning and real-time positioning of drilling tools during implantation surgery. In particular, Navident provides visual, real-time feedback on the location of the working tip of a dental handpiece. It shows

the location and direction of the tip relative to a volumetric CT image of the patient's jaw registered to that anatomy, and, when available, relative to a path planned on that image.

Navident is comprised of the following parts:

- The main system is comprised of a cart that carries a stereoscopic video camera and a laptop with pre-installed proprietary software.
- The Navident system also includes several types of **accessories:**
    - **Jaw motion Tracking Accessories**: Accessories that are rigidly attached to the patient's jaw and are used to maintain the registration between the jaw and its CT image throughout the procedure via real-time tracking of the position of the jaw. They comprise a tag with optical markings trackable by the stereoscopic video camera and a mechanism for rigid attachment of the tag to the patient's Jaw (for tracking the upper jaw only).
    - **Dental Handpiece Tracking Accessories**: Accessories that are rigidly attached to a dental handpiece to be navigated during the dental procedure. They comprise a tag with optical markings trackable by the stereoscopic video camera and a mechanism for rigid attachment of the tag to the handpiece.
    - **Registration accessories**: Accessories that are used in the registration of the patients' anatomy with the patients' CT scan.
    - **Calibrator**: A tool used for calibrating the working tip of the handpiece to determine the geometric relationship between the optical marking on the handpiece-attached tag and the working tip of the surgical instrument.
- Navident's four core functions are:
    - **Model:** Using data imported from CT and intraoral surface scanners, a digital model of the jaw anatomy is compiled and presented to the user.
    - **Plan:** The user, using functions provided by the Navident application software, prepares a digital treatment plan for drilling in bone.
    - **Register:** At the start of the actual treatment, the digital model is aligned with the real anatomy it models. The plan, which was created in geometrical reference to the model can now be referenced, or mapped, to the real anatomy.
    - **Guide:** The tooltip (the working end) of the treatment tool, usually a handpiece with an exchangeable tip, is dynamically shown to the user relative to the (registered) model and the treatment plan.

The user uses the on-screen guidance to align the tooltip with the planned tooltip path to ensure correct and accurate execution of the plan. During surgery, Navident automatically tracks the handpiece's motions. When the handpiece approaches a pre-planned implant location, Navident provides a cross-hairs dynamic visualization of the drill pose relative to the planned pose of the implant. This visualization guides the hand motions of the surgeon towards precisely locating the planned entry point, adjusting the drill axis to the planned angle, and drilling to the planned depth. When the tip is away from a marked implantation path, Navident provides real-time visual feedback showing the CT image intensities in the region surrounding the drill's tip.

The Navident is intended for the drilling of osteotomies for dental implant placement with high-speed and low-speed dental handpieces This submission focuses on modification of the Navident predicate device (K161406) to include additional components including enabling the wireless connection, use of bone screws for edentulous patients, additional patient tracker designs, and a tracing method for registration.

Performance Data

Navident's performance testing included:

- **Reprocessing validation:**
    - **Manual and automated cleaning validation:** manual and automated cleaning validation was performed on representative devices to confirm that the cleaning processes of Navident's accessories can reduce the organic soil load, per AAMI TIR 30: 2011(R) 2016, to:
        - Proteins :< 6.4 µg/cm2
        - Hemoglobin :< 2.2 µg/cm2

      The validation demonstrated that the cleaning process included in Navident's labeling can reduce the soil load to an acceptable level.
    - **Sterilization Validation:** Representative master devices of the re-usable Navident accessories were tested to validate that the components can withstand the steam sterilization process and that acceptable sterility is achieved using the recommended sterilization protocols. The sterilization validation testing was conducted according to ISO 17665-1:2006 (R) 2013 and it validated that the re-usable Navident components can be sterilized to reach an acceptable sterility assurance level.
- **Biocompatibility Testing:**

  The patient contacting Navident components are considered tissue contacting for a duration of less than 24 hours. The components were either tested according to the ISO 10993-1 series or a justification for not performing tests was provided per the FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."
- **Software:**

  Software documentation for moderate level of concern per the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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

  Comprehensive performance testing has been conducted on the Navident device in accordance with the latest recognized industry standards, by an accredited NRTL. Product Safety was evaluated for compliance with IEC 60601- 1:2005 Edition 3.1 ANSI/AAMI ES60601-1:2005 / 2012 and C1:2009/ 2012 and A2:2010/ 2012 (Consolidated Text) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. Electromagnetic Compatibility was assessed for compliance with IEC 60601-1-2:2014 Edition 4.0.

  Evaluation assessment of the wireless technology was conducted per FDA Guidance "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff."

- **Full system accuracy bench testing:**

  The navigation information provided to the user is based on the mapping of the drill tip pose to the CT image data. The accuracy of this mapping is determined by two key factors: (1) the accumulation of errors through the sequence of real time coordinate system mappings and (2) the stability of the coupling between the patient's reference tag and the patient's anatomy. Accordingly, to assess the overall system accuracy, the following bench tests were performed:

  - System accuracy test: to measure the accuracy of the mapping between drill tip poses and image space.
  - Assess the stability and repeatability of the patient reference tag coupling to the patient's jaw:
    - Stability of the Attachment of the Jaw Tracker S to the patient's Jaw
    - Stability of the Attachment of the Jaw Tracker C to the patient's Jaw
    - Stability of the Attachment of the Jaw Tracker B to the patient's Jaw
    - Stability of the Attachment of the Jaw Tracker U to the patient's Jaw

  In all instances, the Navident device functioned as intended and the results observed was as expected.

- **Human factors/usability:**

  Summative evaluation was conducted on the Navident system within a realistically simulated clinical setting. Fifteen (15) representative users (i.e., oral surgeons, general dental practitioners) were observed performing representative and high-risk tasks with the Navident system while test administrators monitored the proceedings for any use errors, close calls or operational difficulties that may be indicative of use-safety or usability problems. The assessment of the test results demonstrated that the Navident system satisfies the identified user specifications for use by qualified dentists for its intended use. Minor findings of the evaluation were thoroughly analyzed and design improvements to Navident were made to address them prior to the current submission.

- **Clinical Literature:**

Clinical evidence supporting the performance of the device was collected from published scientific literature. The described studies were conducted outside of the US; however, the patient populations, user profiles, use environment, and clinical practices are considered equivalent and applicable to the US population.

Three studies were identified which support the substantial equivalence of the Trace registration method. The first study[1] reports on the accuracy results of 136 implants placed under dynamic guidance using the trace registration method in 59 partially edentulous patients. Thirty-nine (39) cases involved the maxilla (75 implants) and 36 cases involved the mandible (61 implants). The mean deviation between the planned and actual position for all implants was 0.67 mm at the entry point, 0.9 mm the apex, 0.55 mm in depth and 2.50° as angular deviation. Tracing 5-6 teeth for registration significantly improved all accuracy outcomes compared to tracing only 3-4 teeth. The 95th percentile values were also computed for the present trace registration method and compared with corresponding measurements taken in an earlier study[2] using a thermoplastic stent and fiducial marker-based registration (the registration method that was cleared for the predicate Navident device K161406). This data was previously collected and published by the same authors and the same surgeon using the stent approach with the same navigation system. The results demonstrated that using trace registration was favorable compared to fiducial-based registration especially when tracing 5-6 teeth.

In another study[3] Stefanelli et al. compared the accuracy of Pterygoid implant placement using dynamic navigation with trace registration versus free hand surgery. In this study 63 pterygoid implants were placed in 39 partially edentulous patients. Thirty-one (31) pterygoid implants were placed using dynamic navigation and trace registration and 32 pterygoid implants were placed using freehand surgery. The mean deviations between the planned and actual position for pterygoid implants placed using dynamic navigation via trace registration was 0.66 mm at coronal level, 1.13 mm at apical level, 0.67 mm in depth, and 2.64° as angular deviation compared to 1.54mm, 2.73mm, 1.17mm and 12.49°, respectively, when freehand surgery alone was used. Pterygoid implants placed using dynamic navigation technology was more accurate when compared to the prosthetically directed presurgical plan in relation to the greater palatine canal and took less surgical time.

In conclusion, one of the main changes introduced by the Navident device in comparison to the predicate Navident device is the addition of another registration method (Trace) on top of the previously available stent and fiducial registration. The accuracy of this registration method was evaluated on 136 implants and was found to be as accurate as fiducial base registration. In addition, the trace registration method was used with 31 Pterygoid implants while comparing to free hand surgery. The results were in favor of the use of dynamic navigation with trace registration.

References:

1) *Stefanelli LV, Mandelaris GA, DeGroot BS, Gambarini G, De Angelis F, Di Carlo S. Accuracy of a Novel Trace-Registration Method for Dynamic Navigation Surgery. Int J Periodontics Restorative Dent. 2020 May/Jun;40(3):427-435.*

2) Stefanelli LV, DeGroot BS, Lipton DI, Mandelaris GA. Accuracy of a Dynamic Dental Implant Navigation System in a Private Practice. Int J Oral Maxillofac Implants. 2019 January/February;34(1):205–213.

3) Stefanelli LV, Graziani U, Pranno N, Di Carlo S, Mandelaris GA. Accuracy of Dynamic Navigation Surgery in the Placement of Pterygoid Implants. Int J Periodontics Restorative Dent. 2020 Nov/Dec;40(6):825-834.

Substantial Equivalence

The current Navident is substantially equivalent to the cleared Navident (K161406). Navident has similar intended use, technological characteristics, and principles of operation as its predicate device. The technological differences between the Navident and its predicate devices raise no new issues of substantial equivalence and its substantial equivalence is further supported by a comparison to a reference device that offers the same intended use and very similar technological characteristics. Performance data demonstrate that Navident is substantially equivalent to the cleared Navident. A comparison of the proposed Navident device to the currently marketed predicate Navident and the reference X-Nav's X-Guide are provided in Table 5-1 below:

Table 5-1: Comparison of Indications for use and Technological Characteristics

Feature/ Characteristic	**Proposed Navident**	**ClaroNav's Navident K161406 (Predicate device)**	**X-Nav's X-guide device K200662 (Reference Device)**	**Justification of difference**
Intended Use				
Class/Product Code/Classification Name	Class II/ PLV/21 CFR 872.4120 (Bone Cutting Instrument and Accessories)	Class II/ PLV/ 21 CFR 872.4120 (Bone Cutting Instrument and Accessories)	Class II/ PLV/ 21 CFR 872.4120 (Bone Cutting Instrument and Accessories)	Identical
Indications for Use	Navident is a computerized dental navigational system intended to assist preoperative planning and to guide drilling in a patient jaw during implantation surgery, using pre-acquired CT scan of the jaw. The device is intended for use by a qualified dental surgeon in the treatment of **partially or fully edentulous jaws**.	Navident is a computerized dental navigational system intended to assist preoperative planning and to guide drilling in a patient jaw during implantation surgery, using pre-acquired CT scan of the jaw. The device is intended for use by a qualified dental surgeon in the treatment of partial edentulism.	The X-Guide® Surgical Navigation System is a computerized navigational system intended to provide assistance in both the preoperative planning phase and intra-operative surgical phase of dental implantation procedures. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments. The device is intended for use for **partially edentulous and edentulous** adult and geriatric patients who need dental implants as part of their treatment plan.	Navident has the same intended use as the predicate device. Navident expands the cleared indication for use of the predicate device from partially edentulous patients to partially edentulous and edentulous patients. Hardware components (Jaw Tracker B) and alternative registration method (Bone screws) are offered in the Navident to support edentulous patients. The reference device, which is also a dental navigation system that uses similar technology, offers similar technological solutions for edentulous patients and has identical intended use and indications for use as the Navident.
Main functions	CT-based placement planning of dental procedures. Presentation of position, angle and depth indicators when drilling in or cutting the jaw.	CT-based implant placement planning. Presentation of position, angle and depth indicators when drilling in the jaw.	CT-based implant placement planning. Presentation of position, angle and depth indicators when drilling in the jaw.	Identical
Use Environment	Dental clinic	Dental clinic	Dental clinic	Identical

Target Population	Adult patients	Adult patients	Adult patients	Identical
Users	Dental surgeons	Dental surgeons	Dental surgeons	Identical
Technological Characteristics				
Input imaging modality	CT	CT	CT	Identical
Dynamic object poses measurement technology	Stereoscopic triangulation of checker-board contrast patterns.	Stereoscopic triangulation of checker-board contrast patterns.	Stereoscopic triangulation of checker-board contrast patterns.	Identical
Handpiece tracking attachment	a visually marked tag.	a visually marked tag.	a visually marked tag.	Identical
Jaw tracking attachment (Dentate Patients)	• "**NaviStent**": molded thermoplastic sheet with an integrated arm holding an optically marked plastic tag. OR: • "Jaw Tracker": optically marked flat tag attached to a hand-configurable stainless steel wire attached to the jaw at its other end. o The **JawTracker C and S** version attaches to a tooth, crown or abutment using approved dental composite resin and bonding agent. o The **JawTracker U** version attaches to several adjacent teeth using a U-shaped clamp filled with bite registration material.	"**NaviStent**" molded thermoplastic sheet with an integrated arm holding an optically marked plastic tag. No support for edentulous jaws.	**X-Clip**®, is attached to patient teeth using an impression material (low temperature thermoplastic). The Patient Tracker which includes the tracking patterns that is visualized by the tracking camara is firmly attached to the X-Clip. This device remains on the patient teeth for the duration of surgery.	Navident offers an identical solution for Jaw tracking (the NaviStent) as the cleared Navident device. In addition, two alternative jaw attachment solutions are offered (JawTracker C and JawTracker U). While the materials used for the attachment (thermoplastic, PVS, composite) and their hardening methods (cooling, chemical or light curing) vary, they are all moldable dental materials in common usage, with well-known properties.

Jaw Tracking Attachment (Edentulous Patient)	**JawTracker B**: optically marked flat tag attached to a hand-configurable stainless steel wire attached to the jaw bone using 3 small bone screws.	None	**Edentulous Clip®** - fixated into position on the patient's jaw using bone screws. The patient tracker, which includes the tracking patterns that is visualized by the tracking camara is firmly attached to the Edentulous Clip. This device remains on the patient teeth for the duration of surgery.	Navident's Jaw Tracker B solution is very similar to the Edentulous clip of the reference X-Guide device, and is based on an optically marked tag that is attached to the patients Jaw using a small plate that is fixated into position on the patient's jaw using bone screws.
Patient to CT image registration	• **NaviStent:** includes a removable CT Marker part containing a CT-visible fiducial body. • **Trace Registration:** registration based on Anatomical Landmarks on the jaw's surface.. • **Bone screws:** placed in the patient's Jaw prior to CT scan to create fiducials. • **NaviBite:** plastic appliance containing several screws with their heads exposed. Used with impression material to form a bite registration plate that can be repeatably coupled to both jaws.	**NaviStent:** includes a removable CT Marker part containing a CT-visible fiducial body.	• **X-Clip:** contains embedded radiodense spheres used as fiducial. • **Bone hole Fiducials:** For edentulous patients, the surgeon drills several narrow holes in the bone to serve as fiducials for the CT scan. • **X-Mark:** registration based on Anatomical Landmarks. • **Bone screws:** placed in the patient's Jaw prior to CT scan to create artificial landmarks.	Navident's registration solutions are identical or very similar to the ones offered in the predicate and the reference devices: • The Navistent is a fiducial based registration, identical to Navident's cleared registration solution (K161406). • The "Trace Registration" is very similar to X-Guide X-mark registration solution. Both are based on existing anatomical landmarks as fiducials. These landmarks are manually marked in the Software and are traced by touching them with the tip of an optically trackable tracer tool. • Bone Screw: same as offered by X-Guide reference device, the bone screws are placed in the patient's Jaw prior to CT scan to create artificial landmarks. • NaviBite: The screw heads, anchored to the NaviBite plastic shell, function very similarly to the spheres embedded in the X-Clip solution of X-Guide. In the registration process, both are touched by a special pointer to provide their location

				relative to the optical markings on the tag coupled to the jaw.
Drill tip calibration	Initial drill axis calibration on a tracked pin, plus tip calibration by placing the tip in a dimple in a special optically marked tool (Calibrator) after each drill change. Support for both low speed and high-speed handpieces	Initial drill axis calibration on a tracked pin, plus tip calibration by placing the tip in a dimple in the Jaw Tag after each drill change.	Initial handpiece calibration using a special optically marked tool, plus tip calibration by touching a point after each drill change.	The calibration steps are similar. In the cleared Navident device, the jaw tag was used to also perform these calibration steps, eliminating the need for a separate tool. The Navident, offers a dedicated calibration tool, same as the reference device (X-Guide).
Mount for camera and display	Mobile cart weighing 55lb with a folding arm holding camera and screen above patient's chest.	Mobile cart weighing 55lb with a folding arm holding camera and screen above patient's chest.	Mobile cart with a large arm holding camera above patient's head. Screen is attached to cart pole.	Identical to the cleared Navident device
Presentation of navigation guidance	3D graphics presentation of drill position, angle and depth relative to planned placement.	3D graphics presentation of drill position, angle and depth relative to planned placement.	3D graphics presentation of drill position, angle and depth relative to planned placement.	Identical to the cleared Navident device
Illumination of tracking targets	Visible light emitted by LED panel (optional)	Visible light emitted by LED panel (optional)	Visible light emitted by LED panel (optional)	Identical to the cleared Navident device
Performance Characteristics				
Accuracy at the drill tip	≤1.0mm	≤1.0mm		Identical to the cleared Navident device
Presentation update rate	Real time	Real time		Identical to the cleared Navident device

Conclusions

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