DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 8, 2016

ClaroNav Inc.
Doron Dekel
CEO
1140 Sheppard Avenue West, Unit 10
Toronto, Ontario M3K 2A2
Canada

Re: K161406
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: August 9, 2016
Received: August 15, 2016

Dear Doron Dekel:

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 yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental 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)*
K161406

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 partial edentulism.

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 Inc.
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Contact Person:	Doron Dekel, CEO
Date Summary Prepared:	September 2 , 2016

DEVICE IDENTIFICATION

Trade/Proprietary Name:	Navident
Classification:	II
Generic Device Name:	Surgical Navigation System
Product Code:	PLV
Classification Names:	Bone Cutting Instrument and Accessories
Classification Regulation #:	CFR 872.4120
Classification Panel:	Dental
Predicate Devices:	X-Guide Surgical Navigation System (k150222)

DEVICE DESCRIPTION

Navident is a cart-based, computerized, image-guided dental navigational system, operating as a combined package for performing both pre-operative planning and guided implant insertion. Using pre-acquired CT scan of the jaw, Navident provides the dentist (usually a GP dentist, prosthodontist, periodontist or dental surgeon) with implantation planning and real-time guidance during dental implants insertion.

The guidance function of Navident is primarily provided using a visualization of the drill pose (tip location and shaft axis direction) relative to the desired pose of the implant, as planned on a pre-acquired CT image of the jaw. This visualization assists the dentist in implementing their implantation plan.

Navident consists of four main components:

1. A notebook computer positioned above the patient's chest. The Navident software running on the computer provides both planning and navigation functionalities.
2. A handpiece attachment. The attachment consists of a universal removable metal adapter, and a specially marked plastic part, named DrillTag, which latches on the adapter.
3. A customizable patient jaw attachment consisting of a moldable stent part, named NaviStent, and a matching specially marked plastic tag, named JawTag. NaviStent can be formed, customized and tested for fit directly on the patient's jaw or on a plaster model. The patient wears the NaviStent during the CT scan and again during the surgery. Navident is able to continuously register NaviStent's position during surgery with its appearance in the CT scan automatically.
4. An optical position sensor which detects high contrast patterns printed on the DrillTag and JawTag and constantly reports their relative positions to the Navident software.

To allow Navident to provide accurate guidance, the dentist fits the NaviStent retainer to the patient's jaw in a chair-side process. The fit can be evaluated to ensure predictable results.

A special CT-Marker is connected to the NaviStent, and the patient is CT-scanned with the NaviStent in place, as with any CT-guide stent. The CT data is loaded into Navident and an implant placement plan is prepared by the surgeon.

Prior to start of drilling for implants, NaviStent is placed in the patient’s mouth, the DrillTag is latched on the tag adapter, and the drill axis location is calibrated in a single motion. When a new drill is inserted, its length and exact tip position are calibrated by touching a dimpled point on the JawTag prior to inserting it into the mouth.

During surgery, Navident automatically tracks the handpiece's motions. When the drill 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 locating the planned entry point, adjusting the drill axis to the planned angle, and drilling to the planned depth. When not near a marked implantation path, Navident provides real-time visual feedback showing the bone densities in the region in front of the drill's tip.

INDICATIONS FOR USE

Navident has the following Intended 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 partial edentulism.*

SUBSTANTIAL EQUIVALENCE

Navident shares technological, performance and clinical features and has substantially equivalent intended use as the X-Guide Surgical Navigation System:

Predicate Company	**Predicate Trade Name**	**510(k) #**	**Predicate Indications for Use**
X-NAV Technologies	X-Guide Surgical Navigation System	K150222	The X-Guide ® Surgical Navigation System is a computerized navigational system intended to provide assistance in both 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 require dental implants as part of their treatment plan.

Comparison of Technological Characteristics

Navident shares many clinical, technological and performance characteristics with a predicate device, the X-Guide Surgical Navigation System. These characteristics are outlined in the following table:

Feature/ Characteristic	**X-Guide (predicate)**	**Navident**	**Rationale for any differences**
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)	Same

Indications for Use	The X-Guide® Surgical Navigation System is a computerized navigational system intended to provide assistance in both the preoperative planning phase and the 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 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.	Since Navident's indications are a subset of the predicate's, each case in which Navident is used is indicated for the predicate as well.
Main functions	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.	Same
Use Environment	Dental clinic	Dental clinic	Same
Target Population	Adult and geriatric patients	Adult patients	Same
Users	Dental surgeon	Dental surgeon	Same
Technological Characteristics			
Input imaging modality	CT	CT	Same
Dynamic object pose measurement technology	Stereoscopic triangulation of illuminated checker-board patterns (X-Corners).	Stereoscopic triangulation of illuminated checker-board patterns (X-Points).	Similar technology with some differences in implementation details.
Handpiece tracking attachment	An optically marked tube-like attachment to the back of the handpiece.	Universal adapter for any handpiece with a visually marked lightweight disposable plastic tag.	Both systems provide a rigid handpiece attachment mechanism with some differences in implementation details.

Jaw tracking attachment	U-shaped “X-clip” with a molded thermoplastic insert, mounted on the available dentition. During surgery, a metallic arm holding an optically marked metal cylinder is connected to it.	“NaviStent” molded thermoplastic sheet with an integrated arm holding an optically marked plastic tag.	In both systems, a thermoplastic part is molded to the surface of the jaw to provide a coupling to the teeth. In both systems, the optically tracked object is rigidly connected to the molded part. Differences relate to implementation details.

Patient to CT image registration	Manual, using small fiducial spheres embedded in the X-clip and a jaw tracker calibration process.	Automatic, using a removable CT Marker part containing a CT-visible fiducial body.	In both systems, fiducial objects of known shapes are used to obtain a registration mapping between the patient jaw and the CT image. Navident uses an automated process.
Jaw attachment calibration	Needed prior to each operation. Different procedures depending on the type of attachment.	Not needed.	Navident's automated registration process eliminates the need for this step.
Drill tip calibration	Initial handpiece calibration using a special optically marked tool, plus tip calibration by touching a point after each drill change.	Initial drill axis calibration, plus tip calibration by touching a point in a dimple after each drill change. Only the jaw tag is used.	The calibration steps are similar. However, the jaw tag is used in Navident to also perform these calibration steps, eliminating the need for a separate tool.
Mount for camera and display	Mobile cart weighing 130lb with a large arm holding camera above patient's head. Screen is attached to cart pole.	Mobile cart weighing 55lb with a folding arm holding camera and screen above patient's chest.	Similar.
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.	Same
Illumination of tracking targets	Visible light emitted by LED panel	Visible light emitted by LED panel (optional)	Same
Performance Characteristics			
Accuracy at the drill tip	≤1.0mm	≤1.0mm	Same
Presentation update rate	Real time	Real time	Same

Navident's intended use for planning and guidance of drilling for dental implementations is identical to the intended use of the predicate device. Each clinical case indicated for Navident is indicated for the predicate as well. The components, performance and operational characteristics of Navident are very similar to those of the predicate device. Noticeable differences between the designs of Navident and the predicate device include:

- In the predicate, calibration of the drilling axis requires a separate procedure using a special tool, while Navident provides an automatically triggered process using a pin on the JawTag. Both provide the same mathematical result and use it in the same manner during guidance.
- In the predicate, the user needs to manually calibrate the registration mapping between the patient jaw and its CT image by touching with a pointer small fiducial spheres placed near the jaw both during the CT scan and the surgery. Navident performs registration using fiducial objects placed near the jaw during the CT scan, and automates the process of computing the registration mapping. Both registration procedures produce the same mathematical result and use it in the same manner during guidance.
- Navident is mounted on a cart with an arm enabling the positioning of the optical tracker and screen above the patient's chest.

The above design differences relate solely to the usability and portability aspects of the devices, not to the core functions they perform, which 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
IEC 62366-1 Edition 1.0 2015-02, Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
IEC 62304 First edition 2006-05, 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.
ISO 10993-1 Fourth edition 2009-10-15, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. (Biocompatibility)
AAMI / ANSI / ISO 10993-5:2009/(R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity.
ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
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)
IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
IEC 62471 First edition 2006-07, photobiological safety of lamps and lamp systems. (Radiology)
FDA Guidance Document Applying Human Factors and Usability Engineering to Optimize Medical Device Design, June 22, 2011

SUMMARY OF PERFORMANCE TESTING

Performance testing of the Navident system was conducted in accordance with all the above referenced standards and regulations. All system requirements, including accuracy requirements, were validated thoroughly, and found to be comparable to those of the predicate device.

Navident's performance testing included:

1. Sterilization Validation: A representative sample of the re-usable Navident components 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 and it validated that the re-usable Navident components can be sterilized to reach an acceptable sterility assurance level.

2. Biocompatibility Testing: The patient-contacting Navident components were tested according to the ISO 10993-1 series as follows:
   - Navident components were tested using the MEM Elution test method to assess cytotoxic effects. as per *ISO 10993-5 biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity*. All test method acceptance criteria were met, supporting the conclusion that the Navident component is biocompatible and appropriate for its intended use.
   - Navident components were tested for hypersensitivity reactions following the Maximization Sensitization Test Method which meets the criteria of ISO 10993-10:2010 Biological Evaluation of medical devices Part 10: Tests for Irritation and Skin Sensitization. No evidence of reaction or sensitization of the Navident test article on the test subjects was observed and all acceptance criteria were met.
   - Irritation testing of Navident components was completed following the Oral Mucosal Irritation Study which meets the criteria of SO 10993-10:2010 Biological Evaluation of medical devices Part 10: Tests for Irritation and Skin Sensitization. No evidence of irritation to the test subject's oral mucous membranes was observed and all acceptance criteria were met.

3. Full system bench testing was conducted on the Navigation system. The bench tests evaluated the following operational aspects:
    a. Overall accuracy of the system in mapping the drill tip to the CT image;
    b. Repeatability of the handpiece calibration process;
    c. Effect of different image voxel sizes on the mapping accuracy;
    d. Effect of distance between the tracking camera and the JawTag on mapping accuracy;
    e. Effect of the number of available fiducial corners on mapping accuracy;
    f. Effect of different ambient lighting conditions on mapping accuracy;
    g. Effect of camera warmup time on mapping accuracy;
    h. Effectiveness of the NaviStent fabrication process with a number of random jaw models;
    i. Evaluating possibility of getting the NaviStent locked onto the teeth;
    j. Repeatability of interlocking of CT Marker with Retainer during CT scan;
    k. Impact of autoclaving cycles on Silicon tape strength;
    l. Tag adapter sterilization tolerance;
    m. Effect of ambient temperature on accuracy;
    n. Effect of strong light shining on one of the tags (HDR mode);

    The bench tests were executed as planned, and all of them succeeded in meeting their acceptance criteria. Additionally, the system passed all tests of immunity to electromagnetic interference according to IEC 60601-1-2 while providing accurate drilling guidance.

4. Human factors/usability summative evaluation was conducted on the Navident system under controlled simulated setting. 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, 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. .

5. ClaroNav has collected and compiled clinical, usability and accuracy data related to the application of Navident in clinical practice by a diverse international group of surgeons. The clinical case data collected consisted of 21 cases with 36 guided implantations. In all cases, Navident fully performed its intended function without complications. Accuracy assessment demonstrated that, with Navident's guidance, an experienced user is able to achieve an implant placement accuracy averaging 1.0mm deviation from plan at both entry and apex. The clinical evaluation further consisted of collecting systematic feedback on usage history and professional impressions from 7 surgeons who treated a total 150 patients guided by Navident. No significant patient adverse events or complications were reported by any participating surgeon.

CONCLUSION

Navident is substantially equivalent to its predicate in its indications for use, principles of operation, technical characteristics, performance and usability as demonstrated using a comprehensive comparison of all relevant characteristics, and by thoroughly testing all key aspects of Navident's performance.