DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 8, 2015

X-Nav Technologies, LLC.
Mr. Fred Cowdery
Director- Regulatory Affairs
1555 Bustard Road, Suite 75
Lansdale, PA 19446

Re: K150222
Trade/Device Name: X-Guide® Surgical Navigation System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: PLV
Dated: September 14, 2015
Received: September 15, 2015

Dear Mr. Cowdery:

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" (21CFR 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,

for Erin I. Keith, M.S.
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)*
K150222

Device Name
X-Guide(R) Surgical Navigation System

Indications for Use *(Describe)*
The X-Guide(R) 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 require dental implants as part of their treatment plan.

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
(As required by Section 807.92)

Date Prepared: October 8, 2015

Applicant:
X-NAV Technologies, LLC
1555 Bustard Road, Suite 75
Lansdale, PA. 19446

Contact Person:
Fred Cowdery
Director – Regulatory Affairs and Quality Assurance
Ph 267-436.0414
Email: fred.cowdery@x-navtech.com

Device Trade/Proprietary Name: X-Guide® Surgical Navigation System,
Model P007839

Device Name: Common / Usual: Surgical Navigation System

Classification Name: 21 CFR 872.4120 (Bone Cutting Instrument and Accessories)

Regulatory Class: II

Product Code: PLV (Dental Stereotaxic Instrument)

Predicate Device(s): IGI-System™ by DENX Advanced Dental Systems Ltd. (K023424)

Device Description:

The X-Guide® Surgical Navigation System is an electro-optical device designed to aid dental surgical procedures by providing the surgeon with accurate surgical tool placement and guidance with respect to a surgical plan built upon Computed Tomographic (CT scan) data.

The system provides the surgeon with a three-dimensional real time video visual aid to indicate dental drill location in space, with 6 degrees of freedom (X, Y, Z, Pitch, Yaw, and Roll) and an accuracy (RMS) of < 1 mm. This helps to improve the Oral Surgeon drilling precision within a patient oral cavity. Since the system is video based, the surgeon is still working in the freehand mode, meaning he/she is always in control of the surgery.

The implant process occurs in two stages. Stage 1 is the preplanning of the surgical implantation procedure. The dental surgeon plans the surgical procedure in the Implant Planning Software, XOS®. A virtual implant is aligned and oriented to the desired location in the CT scan, allowing the dental surgeon to avoid interfering with critical anatomical structures during implant surgery. Once an implant has been optimally positioned, the plan is transferred to the X-Guide® Surgical Navigation System in preparation for implant surgery.

In Stage 2 the system provides accurate guidance of the dental surgical instruments according to the pre-operative plan. As the dental surgeon moves the surgical instrument around the patient anatomy, 2D barcode tracking patterns on the Hand Piece Tracker and the Patient Tracker are detected by visible light cameras in a stereo configuration and processed by data processing hardware to precisely and continuously track the motion of the dental handpiece and the surgically-relevant portion of the patient.

The relative motion of the dental handpiece and the patient anatomy, captured by the tracking hardware, is combined with patient-specific calibration data. This enables a 3D graphical representation of the handpiece to be animated and depicted in precise location and orientation relative to a 3D depiction of the implant target, along with depictions of the patient anatomy, and other features defined in the surgical plan. This provides continuous visual feedback that enables the dental surgeon to maneuver the dental handpiece into precise alignment.

Several patient-specific calibrations underpin the guidance system. Hand Piece calibration is performed to determine the geometric relationship between the Hand Piece Tracker and the tip of the surgical instrument.

Likewise, Patient Tracker calibration is performed to determine the geometric relationship between the Patient Tracker and the scan coordinates of the patient anatomy. There are separate procedures for Patient Tracker calibration, depending on whether the X-Clip or the E-Clip is used.

For toothed patients (partially edentulous), an X-Clip®, which contains embedded radiodense spheres, is attached to patient teeth prior to CT image acquisition. The location of these spheres on the X-Clip® establishes a link between the CT coordinate system and the patient's surgical anatomy. Immediately prior to surgery, the Patient Tracker is attached, and a separate calibration determines the relationship between the spheres and the Patient Tracker. This device remains on the patient teeth for the duration of surgery.

For edentulous (toothless) patients, the surgeon drills several narrow holes in the bone to serve as fiducials for the CT scan. Nothing is implanted. After the CT scan and surgical plan are completed, including the step of locating and marking the holes in the CT image, an E-Clip® is attached to the patient just prior to surgery. This device is necessary to attach tracking patterns to facilitate the navigation and tracking process, and is calibrated to the patient anatomy and CT by probing each of the fiducial holes and correlating these locations to the locations marked in the plan.

During execution of the surgical procedure, the X-Guide® Surgical Navigation System correlates between the surgical plan and the surgeon's actual performance. If significant deviations in navigation between the plan and the system performance occur, the system will alert the user.

The X-Guide® Surgical Navigation System is a supporting device, providing additional information to the decision-making process during the surgical procedure. It is by no means intended to replace the surgeon's judgment. The final decisions as to the exact location and depth of the surgery are the sole responsibility of the surgeon. The surgeon can at any time during the surgical procedure modify the planned implant positions. Under no circumstances does the device relieve the surgeon of his or her ultimate clinical responsibility.

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.

Comparison of Technological Characteristics:

The X-GuideR Surgical Navigation System shares clinical, technological, and performance features with a similar FDA cleared tracking device – The Denx Ltd. IGI-System™ (K023424).
Both systems provide accurate guidance of surgical tools and implantable devices through the use of computer aided navigation. This guidance is achieved through the use of optical tracking of the surgical tools.
Neither device is intended to replace human assessment, but to provide objective information relating to the positioning and alignment of the surgical tools or implantable devices in reference to the patient anatomy.

Additionally, the X-GuideR Surgical Navigation System and the predicate device share several other significant features:

- Both devices have the same Intended Use.
- Both devices provides animated indicators to show the real time location of the surgical tool relative to the patient anatomy, showing the tool in the patient CT in real time.
- Both devices employ stereo computer vision tracking techniques.
- Both devices reduce risk of damage to adjacent anatomical structures.
- Both devices share identical specified environments of use.
- Both devices provide Planning Software allowing for placement of implant, target surgical site, and guidance to the implant site.
- Both devices provide sub-millimeter navigation accuracy.
- Both devices use CT Scans for registration of the patient tracking attachment, for use in planning the desired implant location, and as a reference to determine the exact positioning of the surgical tools during the surgical procedure.

There are many similarities between the X-Guide® Surgical Navigation System and the IGI-System™, however there are also some differences, mostly relating to technology and performance.

While the X-Guide® Surgical Navigation System and IGI-System™ both use stereo cameras to gather tracking information, the two systems have a fundamental difference in the tracking mediums and methods used. The IGI-System™ utilizes Infrared LEDs, operating at approximately 1050 nm, configured in an Emitter Collector configuration for tracking whereas the X-Guide® System utilizes a pattern illuminated by an LED array for tracking purposes.

Furthermore, the X-Guide® Surgical Navigation System's feature points are based on contrast saddle-points, whose detected locations are more stable under perturbations (variations in lighting, partial obscuration) than the roughly circular intensity pattern produced by an Infrared LED, resulting in higher theoretical accuracy in surgical environments.

The X-Guide® Surgical Navigation System and IGI-System™ both have provisions for patient and stereo camera alignment within the tracking volume. Since the IGI-System™ cameras can only detect in the infrared spectrum, not allowing for video feedback to aide in the positioning process, lasers are necessary. In the X-Guide® system stereo cameras are positioned visually utilizing video feedback from the stereo cameras.

The X-Guide® Surgical Navigation System and IGI-System™ both attach the Applied Part to the patient. The X-Guide® System Applied part is a Type B whereas the IGI System Applied Part is Type BF. The difference in applied part rating extends from the IGI-System™ applied part being both conductive and utilizing electrical energy on the component. The applied part utilized by the X-Guide® Surgical Navigation System is nonconductive and does not utilize electrical energy, providing a lower risk of electrical shock to the patient in the event of a single fault.

Several times during a surgical procedure it is common for the surgical instrument, (Dental Hand Piece) to exit and enter a "navigation zone", which is essentially the surgical region. Typically, the reason to exit is to change drill bit types and lengths. When the surgical instrument is entering the "navigation zone", the X-Guide® Surgical Navigation System requires the doctor to touch the "Go Button". This action will automatically trigger the calculation of the drill bit length prior to resuming surgery.

Comparison of Technological Characteristics:

	N/A	K023424	
Use Specifications	**X-Guide®**	**IGI-System™**	**Justification of Differences**
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 surgical 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.	The Image-Guided Implantation (IGI) System is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation procedure. The system provides accurate navigational guidance of surgical instruments, with regard to the pre-operative planning in dental implantation procedure. The device is intended for use for partially or fully endentulous patients who need dental implants as part of their treatment plan.	There is no difference between the products in Intended Use. The X-Guide® Surgical Navigation System specifies a target population, whereas the IGI-System™ does not.
Use Environment	Clinical Setting, Doctors Office	Clinical Setting, Doctors Office	No Difference

	N/A	K023424	
Technology / Performance Characteristics	**X-Guide®**	**IGI-System™**	**Justification of Differences**
Operating Temperature	10 - 35 deg C	Not specified	Both systems are intended for use in similar clinical environments.
Operating Relative Humidity	30% - 90% non-condensing	Not Specified	Both systems are intended for use in similar clinical environments.
Altitude	500 hPa-1060hPa	500 hPA – 1060 hPA	No Difference
Transport Temperature	-20 - +60 deg C	0 - 40 deg C	The X-Guide® can withstand a wider range of storage / transport temperature without compromising system integrity
Transport Humidity	10% - 95% non-condensing	10% - 80% non-condensing	The X-Guide® can withstand a higher level of humidity during transport without compromising system integrity.
Optical Radiation	LED, Risk Group 1 (minimal risk) per IEC 62471-1	Laser, Class II (<1mW) per IEC 60825-1, 620-690nm	No Difference in Risk Level
Tracking Technology	Stereo Cameras / LEDs / Pattern	Stereo Cameras / Infrared LEDs	X-Guide® Surgical Navigation System uses passive elements on the patient for tracking purposes whereas the IGI-System™ uses active elements (containing electrical energy) attached to the patient for tracking purposes.
Calibration Frequency	Prior to each surgery	Factory Calibrated and authorized service personnel.	No Difference
Overall System Accuracy (RMS)	<1mm	<1 mm	No Difference
Alarms	Audible, Visual	Audible, Visual	No Difference
Monitor	LCD-TFT	LCD-TFT	No Difference
Communications Interface	Ethernet	Ethernet	No Difference
Software	Navigational Guidance and Implant Planning	Navigational Guidance and Implant Planning	No Difference

	N/A	K023424	
Technology / Performance Characteristics	**X-Guide®**	**IGI-System™**	**Justification of Differences**
Dimensions	Height: 64.653 in (1642.19 mm) Width: 21.011 in (533.67mm)	Unavailable	Both systems are intended for use in similar clinical environments and are classified as mobile per IEC / EN 60601-1definition.
Mounting Configuration	Mobile Cart	Mobile Cart	No Difference
Weight	130lbs. (58.97 kg)	Unavailable	Both systems are classified as Mobile, per IEC / EN 60601-1definition. Differences in weight that may exist do not affect either devices efficacy or intended use.

Safety Features	**X-Guide®**	**IGI-System™**	**Justification of Differences**
Electrical Safety	IEC 60601-1:2005 3rd Edition AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006 ISO15223-1:2012 BS EN ISO 14971:2012	EN60601-1:1990 +A1:1992 +A2: 1995; +A13 IEC 601-1:1998 +A1:1991 +A2:1995 +Corrigendum EN60601-1-1:1993 +A1:1995 IEC60601-1-4:1996 EN980:1996 +A1:1999 EN1441:1997	The X-GuideR system has been certified to more recent editions of the Electrical Safety Standards, which have a heavier influence of ISO 14971 Risk Management. EN60601-1-1 and IEC 60601-1-4 have been merged into the 3rd edition of EN60601-1:2006 and IEC60601-1:2005. Therefore both system were evaluated to the same standards. While both standards provide guidance for symbolic labeling of medical devices, ISO 15223-1:2012 is an FDA recognized standard. While both standards provide guidance for evaluating risk in medical devices, ISO 14971:2012 is an FDA recognized standard.
Electromagnetic Compatibility	IEC 60601-1-2:2007 3rd Edition	EN 60601-1-2:1993 IEC 601-2:1993	The X-Guide® was evaluated to the 3rd edition of IEC60601-1-2:2007 which contains more stringent requirements for EMC Compliance.
Biocompatibility	Yes (ISO 10993-1, -5, -10, -11, -12)	not specified	Do not anticipate any significant difference in this characteristic since both systems are intended for use in similar clinical environments.
Sterilization	Steam	Steam	No Difference
Disinfectant (High-Level)	3% Glutaraldehyde solution	3% Glutaraldehyde solution	No Difference

Safety Features	X-Guide^{R}	IGI-System™	Justification of Differences
Ingress Protection	IP2X	Not Specified in IFU or Product Labeling	Do not anticipate any significant difference in this characteristic since both systems are intended for use in similar clinical environments.

	N/A	K023424	
Energy	**X-Guide®**	**IGI-System™**	**Justification of Differences**
Mains Voltage, Frequency	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	100VAC /120VAC / 230VAC 50 / 60 Hz	No significant difference – Both systems are configurable to operate over the same voltage and frequency ranges.
Input Power (VA）	1500VA	260VA	The X-Guide^{R} system Computer utilizes high performance video cards for data processing and contains and LED Lighting Module which accounts for most of the system power.
Fusing Type / Rating	Circuit Breaker: 100-127VAC, 10A	Fuse: Qty 2 @ 6A/100-120VAC	Both components perform the same function. The difference between the components is that a Circuit Breaker can be manually reset whereas a fuse requires replacement.
Degree of Protection Against Electrical Shock	Applied Part Type B	Applied Part Type BF	The X-Guide^{R} applied part (X-Clip) which attaches to the patient for tracking patient motion is made of a non-conductive material and does not deliver electrical energy. Since the IGI-System™ applied part contains electrical energy, it is classified in a higher risk category (, Type BF) for protection against electrical shock,
Type of Protection Against Electrical Shock	Class I	Class I	No Differences
Mode of Operation	Continuous	Continuous	No Differences

	N/A	K023424	
Components	**X-Guide®**	**IGI-System™**	**Justification of Differences**
Bone Screw	Bone Screw	Bone Screw	Intended use for this item is the same for both systems.
CT Registration	X-Clip	Custom Registration Device (CRD) And 3 Point Touch Registration Fixture	Intended use for these items is the same for both systems.
Patient Tracking Device	X-Corner Patient Tracker	Patient Tracker	Intended use for these items is the same for both systems.
Surgical Tool Tracking Device	X-Corner Handpiece Tracker	Handpiece Tracker	Intended use for these items is the same for both systems.
Screwdriver	Yes	Yes	Intended use for these items is the same for both systems.
Endentulous Patient Tracking Attachment System	E-Clip	Splint	Intended use for these items is the same for both systems.
Drill Bit Length Determination	Go Button	Operator Entry required	X-Guide® Drill Bit length measurement and recording process is automated with the use of the Go-Button. The IGI-System requires the surgeon to manually enter the correct drill bit length.
Patient Tracker Attachment Arms	Posterior Tracker Arm Anterior Tracker Arm	6 Poles – 3 Upper, 3 Lower	Intended use for these items is the same for both systems.

Performance Testing:

Biocompatibility testing

The biocompatibility evaluation for the X-Guide® Surgical Navigation System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous
- Systemic toxicity

The components of the X-Guide® Surgical Navigation System are considered tissue contacting for a duration of less than 24 hours.

Electrical Safety and Electromagnetic Compatibility (EMC)

Comprehensive performance testing has been conducted on the X-Guide® Surgical Navigation System in accordance with various recognized industry standards, by a recognized third party organization. The system complies with IEC 60601-1:2005 3rd edition, ANSI/AAMI ES 60601-1, IEC 62471-1:2006, ISO 14971:2012, IEC 60601-1-6:2010 and IEC62366:2007 for product safety and IEC 60601-1-2:2007 for EMC Safety.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in result in minor injury to the patient or operator.

The combined testing and analysis of results provides assurance that the device performs as intended.

Non-clinical Comparisons to Predicate Device:

Hardware and software verification and validation testing has been performed at the system level to confirm the performance of the X-Guide® and assess substantial equivalence claims to the predicate device.
Internal Validation testing was conducted in a simulated clinical environment at the system and component level. The differences between the proposed and predicate devices are limited to differences in design, material, and operation.

Clinical Testing:

Clinical testing has been conducted to assess the accuracy, usability, and performance of the X-Guide®. Clinical Test results indicate the X-Guide® is at least as accurate as the predicate device, IGI-System (K023424) supports our claim of navigation accuracy < 1 mm and substantial equivalence.

Over 150 patients participated in the study. The patient population included both adult and geriatric, male and female patients. After 7 months of testing in a clinical environment, no adverse events or complications have been identified or reported.

Clinical testing was conducted by Board Certified Oral Surgeons and testing was conducted at their facilities. While each doctors Operatories have similar capabilities, the configuration of each operatory can vary. Therefore, Usability was assessed from a doctor and system perspective. Risks associated with Usability have been properly mitigated through product design. In comparison to the predicate device, no new Usability issues or risks have been identified.

Substantial Equivalence:

The X-Guide® Surgical Navigation System is believed to be substantially equivalent to currently marketed Surgical Navigation Systems with regards to intended use and performance.
Similar to the predicate devices, the X-Guide® Surgical Navigation System provides positioning data to indicate the location of a Dental Handpiece in space during navigation. An LED Monitor provides a visual aide to the surgeon for procedural support during the execution of surgical procedures.

Conclusions:

The differences between the proposed and predicate devices are limited to differences in design, material, and operation.

Based upon the information provided within this 510(k) Premarket Notification, we conclude that the X-Guide® Surgical Navigation System is substantially equivalent to the identified predicate devices when used as intended.