February 21, 2024

X-Nav Technologies, LLC
Kimberly Chan
Director of Regulatory Affairs and Quality Assurance
1555 Bustard Road
Suite 75
Lansdale, Pennsylvania 19446

Re: K232148
Trade/Device Name: X-Guide Surgical Navigation System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: QRY, PLV
Dated: January 24th, 2024
Received: January 24th, 2024

Dear Kimberly Chan:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
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.

Submission Number *(if known)*

K232148

Device Name

X-Guide Surgical Navigation System

Indications for Use *(Describe)*

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 and/or endodontic access procedures.

The system provides software to preoperatively plan dental implantation procedures and/or endodontics access 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 a part of their treatment plan. The device is also intended for endodontic access procedures (i.e., apicoectomies and/or access of calcified canals) where a CBCT is deemed appropriate 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.

510(k) Summary – K232148

(As required by Section 807.92(c))

Date Prepared:	21 FEB 2024
Applicant:	X-Nav Technologies, LLC 1555 Bustard Road, Suite 75 Lansdale, PA. 19446
Contact Person:	Kimberly Chan Director of Regulatory Affairs and Quality Assurance Phone: 267-436-0414 regulatory@x-navtech.com
Device Trade / Proprietary Name:	X-Guide Surgical Navigation System Model P007839 Model P011000
Device Name, Common/Usual:	Surgical Navigation System
Classification Name:	21 CFR 872.4120 (Bone Cutting Instrument and Accessories)
Regulatory Class:	II
Product Code:	QRY, PLV
Predicate Device:	X-Guide® Surgical Navigation System (K211701)
Reference Devices:	DTX Studio Clinic 3.0 (K213562) NobelClinician®, DTX Studio Implant (K163122)

Proposed Change – Automatic Image Processing (AIP) Software Integration (IconiX)

The proposed change is a software change to integrate a machine learning software trained on varied CT data to segment and identify anatomical structures in a maxillofacial Computer Tomography (CT) scan and in an IntraOral Scan (IOS). The machine learning software performs Automatic Image Processing when a CT or IOS is loaded into the X-Guide System. The software is not adaptive. Rather, it is trained at the manufacturer and the weights are locked.

The AIP initializes upon opening a patient case. The original CT is not altered. All data is displayed is superimposed on the radiographic images, allowing for users to view and confirm the correctness and completeness of results and, if desired, replace or augment them with conventional tools/methods provided in the predicate device.

The machine learning software can recognize the following anatomical features in a CT:

- Teeth (including roots)
- Maxilla bone
- Mandible bone
- Maxillary Sinuses
- Mandibular Nerve Canal

The machine learning software can recognize the following anatomical features in an IOS:

- Teeth
- Gingiva

Additionally, the software may also use the Automatic Image Processing outputs to:

- create a pan curve automatically to fit the arch (minimum of two teeth per sextant required)
- register (superimpose) the IOS over the CT
- generate the X-Guide SurfiX from the segmented teeth and bone for use in X-Mark Registration (point marking) or Refinement.

The subject device is the same as the X-Guide® Surgical Navigation System cleared under K211701 (the predicate device) except for the addition of the machine learning software. There are no changes to the components. There are no changes to the calibration workflow or navigation process.

The differences in software do not affect the safety or effectiveness of the device when used as labeled. The device is still for use with dental surgical procedures under the control of a trained surgeon. 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 trajectories. Under no circumstances does the device relieve the surgeon of his or her ultimate clinical responsibility.

Device Overview

The X-Guide® Surgical Navigation System is a cart mounted mobile system utilizing video technology to track position and movement of a surgical instrument (Dental Hand-Piece) during surgical procedures.

The X-Guide® Surgical Navigation System consists of a Mobile Cart, equipped with an LCD Monitor, Boom Arm, Navigation Assembly, Keyboard, Mouse and an Electronics Enclosure. Reference Figures 1 and 2 for an illustration.

The Electronics Enclosure contains the system power supplies, data processing hardware, and electronics control circuitry for coordinating operation of the X-Guide® Surgical Navigation System.

A LCD Monitor, Keyboard, and Mouse serve as the main user interface for the surgeon. The Go-Button serves as an additional form of input by providing virtual buttons that a user can activate by touching them with the surgical instrument tip.

The Boom Arm allows the operator to manipulate the Navigation Assembly position for optimal distance and alignment to patterns located with the surgical region (Navi-Zone) for tracking purposes. The Boom Arm can be extended up to ~79" in the X-Axis and retracts to ~35". It can be positioned 180 degrees in the left to right to left motion range.

The Navigation Assembly contains two cameras oriented in a stereo configuration, along with blue lighting for illuminating the patterns and mitigating ambient lighting noise.

This electro-optical device is designed to improve 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 surgical process occurs in two stages. Stage 1 is the pre-planning of the surgical procedure. The dental surgeon plans the surgical procedure in the X-Guide System Planning Software. A virtual implant or endodontic trajectory is aligned and oriented to the desired location in the CT scan, allowing the dental surgeon to avoid interfering with critical anatomical structures during surgery. Once an implant or trajectory has been optimally positioned, the plan is transferred to the X-Guide Surgical Navigation System in preparation for 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 Handpiece 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.

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.

Safety glasses are provided for patient use on an optional as needed basis.

Device accuracy has been evaluated for compliance with FDA recognized performance standard ASTM F2554- 18, Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.

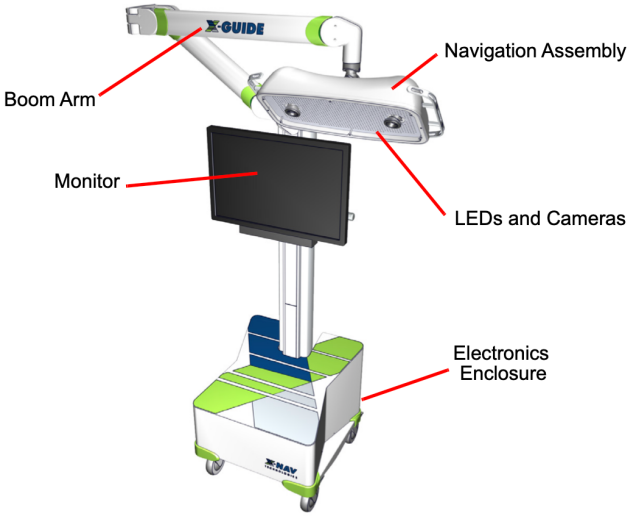

Figure 1: X-Guide® Surgical Navigation System (P007839)

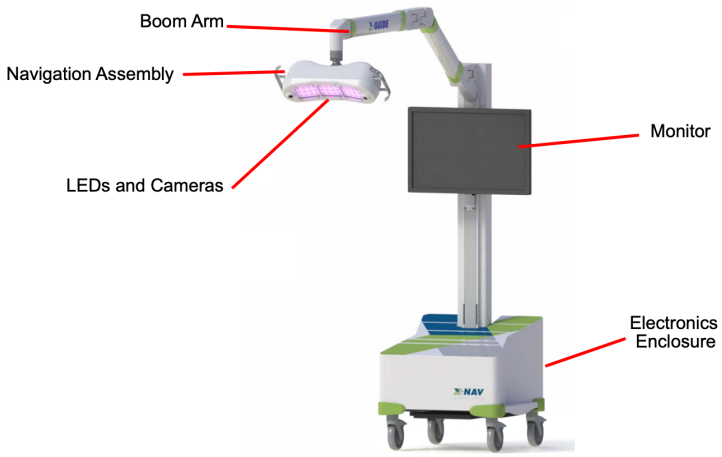

Figure 2: X-Guide® Surgical Navigation System (P011000)

Device Description

The benefit is to improve surgical procedures and reduce risk of potential damage to adjacent anatomical structures and tissues, resulting in a reduction of risk to the patient.

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 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.

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.

Patient Tracker Calibration

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 patient is edentulous, partially edentulous, or if the surgeon wishes to use the X-Mark process.

- **X-Clip Calibration:** 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.
- **Edentulous Fiducial Registration:** For edentulous (toothless) patients, the surgeon drills several bone screws in the bone to serve as fiducials for the CT scan. The location of these bone screws establishes a link between the CT coordinate system and the patient's surgical anatomy. The surgeon then locates and marks the screws in the CT image in the X-Guide software. Just prior to surgery, an Edentulous Clip, CLX Tracker Arm, or EDX Tracker arm is attached to the patient. This device is necessary to attach the Patient Tracker to the patient, and facilitates the navigation and tracking process. The system is calibrated to the patient anatomy and CT by probing each of the fiducial screws and correlating these locations to the locations marked in the plan.
- **X-Mark Registration:** The CT scan of the patient is taken without any fiducials in the image. The doctor manually marks anatomical landmarks as fiducials instead, and because of this, this process is well suited for both dentate and edentulous patients. Once at least 3 anatomical landmarks are marked, the doctor registers the anatomical landmarks by touching them with the tip of a Probe Tool on the registration page. The tracking system tracks the relationship between the Patient Tracker and Probe Tracker to complete the patient registration.

Device 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 and/or endodontic access procedures.

The system provides software to preoperatively plan dental implantation procedures and/or endodontics access 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 a part of their treatment plan. The device is also intended for endodontic access procedures (i.e., apicoectomies and/or access of calcified canals) where a CBCT is deemed appropriate as part of their treatment plan.

Specifications

A comparison of the following specifications is itemized in the tables on the ensuing pages.

- Use Specifications
- Technology / Performance Characteristics
- Safety Features
- Components
- Energy

Use Specifications

Use Specifications	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K211701	DTX Studio Clinic 3.0 **(Reference Device for automatic annotation of the dental mandibular canal) ;** K213562	NobelClinician®, DTX Studio Implant (**Reference Device for the alignment of IOS to CBCT and guidance of surgery);** K163122	**Justification of Differences**
Indications for Use Statement	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 and/or endodontic access procedures. The system provides software to preoperatively plan dental implantation procedures and/or endodontics access 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 a part of their treatment plan. The device is also intended for endodontic access procedures (i.e., apicoectomies and/or access of calcified canals) where a CBCT is deemed appropriate as part of their treatment plan.	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 and/or endodontic access procedures. The system provides software to preoperatively plan dental implantation procedures and/or endodontics access 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 a part of their treatment plan. The device is also intended for endodontic access procedures (i.e., apicoectomies and/or access of calcified canals) where a CBCT is deemed appropriate as part of their treatment plan.	DTX Studio Clinic is a software program for the acquisition, management, transfer and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental restorative solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.	NobelClinician® (DTX Studio Implant) is a software interface for the transfer and visualization of 2D and 3D image information from equipment such as a CT scanner for the purposes of supporting the diagnostic process, treatment planning and follow-up in the dental and cranio- maxillofacial regions. NobelClinician® (DTX Studio Implant) can be used to support guided implant surgery and to provide design input for and review of dental restorative solutions. The results can be exported to be manufactured.	The subject device has the same Indications for Use as the predicate device. The Reference devices are software used in planning dental and maxillofacial surgery. The proposed device modification is limited in scope to a change to the pre-operative treatment planning phase of the software. The pre-operative treatment planning phase of the software displays 2D and 3D images from various sources. A plan generated in NobelClinician®, DTX Studio Implant can be used to fabricate a static guide for use in surgery.
Intended User	Dentists	Dentists	Dentists	Dentists	No difference
Use Environment	Clinical Setting, Doctor's Office	Clinical Setting, Doctor's Office	Clinical Setting, Doctor's Office	Clinical Setting, Doctor's Office	No difference

Technology/Performance Characteristics

Technology / Performance Characteristics	**X-Guide® (Subject Device)**	**X-Guide® (Predicate Device) ; K211701**	DTX Studio Clinic 3.0 **(Reference Device for automatic annotation of the dental mandibular canal) ;** K213562	NobelClinician®, DTX Studio Implant (**Reference Device for the alignment of IOS to CBCT and guidance of surgery);** K163122	**Justification of Differences**
Operating Temperature	10 - 35 deg C	10 - 35 deg C	Not applicable	Not applicable	No difference.
Operating Relative Humidity	30% - 90% non-condensing	30% - 90% non-condensing	Not applicable	Not applicable	No difference.
Operating/Transport Air Pressure	500 hPa-1060hPa	500 hPa-1060hPa	Not applicable	Not applicable	No difference.
Transport Temperature	-20 - +60 deg C	-20 - +60 deg C	Not applicable	Not applicable	No difference.
Transport Humidity	10% - 95% non-condensing	10% - 95% non-condensing	Not applicable	Not applicable	No difference.
Optical Radiation	LED, Risk Group 1 (minimal risk) per IEC 62471-1	LED, Risk Group 1 (minimal risk) per IEC 62471-1	Not applicable	Not applicable	No difference.
Tracking Technology	Stereo Cameras / LEDs / Pattern	Stereo Cameras / LEDs / Pattern	Not applicable	Not applicable	No difference.
Calibration Frequency	Prior to each surgery	Prior to each surgery	Not applicable	Not applicable	No difference.
Overall System Accuracy (RMS)	<1mm	<1mm	Not applicable	Not applicable	No difference.
Alarms	Audible, Visual	Audible, Visual	Not specified	Not specified	No difference.
Monitor	LCD-TFT	LCD-TFT	Not specified	Not specified	No difference.
Communications Interface	Ethernet	Ethernet	Not specified	Not specified	No difference.
Software	Navigational Guidance and Implant/Trajectory Planning	Navigational Guidance and Implant/Trajectory Planning	Acquisition, management, transfer and analysis of dental and craniomaxillofacial image information; design input for dental restorative solutions. It displays and enhances images to support the diagnostic process and treatment planning	Guided implant surgery planning; design input and review of dental restorative solutions	No difference. The reference devices do not include navigational guidance software, however, they can be used to plan dental restorative solutions and/or guided implant surgery. NobelClinician®, DTX Studio Implant can be used to fabricate a static surgical guide.
Navigation Screens	Handpiece Navigation	Handpiece Navigation	Not applicable	Not applicable	No difference

Visualization	Visualize 2D and 3D image data. The user can apply image filters and can measure length, angles and HU units. If found in the CBCT, the Automatic Image Processing (AIP) software will overlay segmented and identified teeth, maxilla bone, mandible bone, maxillary sinuses, and mandibular nerve canals on the CBCT.	Visualize 2D and 3D image data. The user can apply image filters and can measure length, angles and HU units.	Review and diagnose 2D and 3D image data as well as clinical images. The user can apply image filters and can measure length, angles and HU units. Automatic annotation of the mandibular canals based on anatomical landmarks	Review and diagnose 2D and 3D image data to support guided implant surgery and to provide design input for and review of dental restorative solutions	The difference between the subject and the predicate is the subject of this device modification, to allow the addition of AIP to assist in planning. The software automatically segments the teeth, maxilla bone, mandible bone, maxillary sinuses, and mandibular nerve canals. The user can also manually indicate the mandibular canal or manually indicate the tooth surfaces used for X-Mark. This functionality is similar as in the reference device DTX Studio Clinic 3.0 (K213562), which automatically annotates the mandibular nerve canal. The mandibular nerve canal is a high-risk anatomical structure. The other anatomical structures that the AIP is able to segment are of lower or equivalent risk.
Pan Curve Creation	AIP utilizes automatic tooth identifications to generate a proposed panoramic spline curve on the arch. The user may still decide to manually mark points on arch at certain teeth locations. The software generates a panoramic spline curve.	User manually marks points on arch at certain teeth locations. The software generates a panoramic spline curve.	Software automatically generates a proposed panoramic curve.	Software automatically generates a proposed panoramic curve.	The difference between the subject and the predicate is the subject of this device modification, to allow the addition of AIP to generate a proposed panoramic curve. The reference devices automatically generate proposed pan curves.
Surface Definition	AIP utilizes automatic segmentation definitions to generate the surface (“SurfiX”). The user may also manually choose an isosurface HU value (“SurfiX”).	User manually chooses an isosurface HU value (“SurfiX”).	No explicit surface definition. Volume Rendering Transfer Functions with Isovalue Thresholding for visualization	No explicit surface definition. Volume Rendering Transfer Functions with Isovalue Thresholding for visualization	The difference between the subject and the predicate is the subject of this device modification, to allow the addition of AIP to assist in segmentation of anatomy and the definition of surfaces.

IOS Registration	AIP registration of imported IOS to CT Manual Registration of IOS to CT by Point-Matching	Manual Registration of IOS to CT by Point-Matching	SmartFusion™ : directly combining surface models from all intraoral and desktop scanners with any CBCT scan using proprietary voxel-based algorithms Manual Registration of IOS to CT by Point-Matching	This surface information is aligned to DICOM data to support the prosthetic implant planning and guided surgery protocols. Manual Registration of IOS to CT by Point-Matching	The difference between the subject and the predicate is the subject of this device modification, to allow the addition of AIP to assist in IOS Registration. The software automatically superimposes an imported IOS to the CBCT. The user can also manually select points to perform the superimposition in the subject device. This functionality corresponds with the reference device NobelClinician®, DTX Studio Implant (K163122), which allows for the superimposition of the IOS and the CBCT to support implant planning. Nobel Clinician® (K163122) allows the user to fabricate surgical guide templates based on the plan.
Dimensions	Height: 64.653 in (1642.19 mm) Width: 21.011 in (533.67mm)	Height: 64.653 in (1642.19 mm) Width: 21.011 in (533.67mm)	Not applicable	Not applicable	No difference.
Mounting	Mobile Cart	Mobile Cart	Not applicable	Not applicable	No difference.
Configuration Weight	P007839: 102 kg (225 lb) P011000: 100kg (220 lb)	130lbs. (58.97 kg)	Not applicable	Not applicable	Addition of weight to the bottom of the system for better tip-over resistance.

Safety Features

Safety Features	**X-Guide® (Subject Device)**	**X-Guide® (Predicate Device) ; K211701**	DTX Studio Clinic 3.0 **(Reference Device for automatic annotation of the dental mandibular canal) ;** K213562	NobelClinician®, DTX Studio Implant (**Reference Device for the alignment of IOS to CBCT and guidance of surgery);** K163122	**Justification of Differences**
Electrical Safety	IEC 60601-1:2005 Edition 3.2 AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006 ISO15223-1:2012 BS EN ISO 14971:2019 IEC 62304: 2006, A1:2015	IEC 60601-1:2005 Edition 3.1 AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006 ISO15223-1:2012 BS EN ISO 14971:2012 IEC 62304: 2006, A1:2015	Not applicable	Not applicable	Updated for latest Risk Management (ISO 14971) Updated for latest 60601-1
Electromagnetic Compatibility	IEC 60601-1-2:2014 ed 4.1	IEC 60601-1-2:2014 4th Edition	Not applicable	Not applicable	Updated for latest 60601-1-2
Biocompatibility	Yes (ISO 10993-1, -5, -10, -11, -12)	Yes (ISO 10993-1, -5, -10, -11, -12)	Not applicable	Not applicable	No difference
Sterilization	Steam	Steam	Not applicable	Not applicable	No difference
Disinfectant (High Level)	3% Glutaraldehyde solution	3% Glutaraldehyde solution	Not applicable	Not applicable	No difference
Ingress Protection	IP2X	IP2X	Not applicable	Not applicable	No difference

Components

Components	**X-Guide® (Subject Device)**	**X-Guide® (Predicate Device) ; K211701**	DTX Studio Clinic 3.0 **(Reference Device for automatic annotation of the dental mandibular canal) ;** K213562	NobelClinician®, DTX Studio Implant (**Reference Device for the alignment of IOS to CBCT and guidance of surgery);** K163122	**Justification of Differences**
Bone Screw	Bone Screw(s)	Bone Screw(s)	Not applicable	Not applicable	No difference
CT / Patient Registration	X-Clip, Organic Fiducials, Anatomical Landmarks	X-Clip, Organic Fiducials, Anatomical Landmarks	Not applicable	Not applicable	No difference
Patient Tracking Device	X-Corner Patient Tracker	X-Corner Patient Tracker	Not applicable	Not applicable	No difference
Surgical Tool Tracking Device	X-Corner Handpiece Tracker	X-Corner Handpiece Tracker	Not applicable	Not applicable	No difference
Screwdriver	Yes	Yes	Not applicable	Not applicable	No difference
Edentulous Patient Tracking Attachment System	Edentulous Clip, EDX Tracker Arms, CLX Tracker Arms	Edentulous Clip, EDX Tracker Arms, CLX Tracker Arms	Not applicable	Not applicable	No difference
Registration Tool	Probe Tool	Probe Tool	Not applicable	Not applicable	No difference
Drill Bit Length Determination	Go Plate	Go Plate	Not applicable	Not applicable	No difference
Patient Tracker Attachment Arms	Posterior Tracker Arm; Anterior Tracker Arm	Posterior Tracker Arm; Anterior Tracker Arm	Not applicable	Not applicable	No difference

Energy

Energy	**X-Guide® (Subject Device)**	**X-Guide® (Predicate Device) ; K211701**	DTX Studio Clinic 3.0 **(Reference Device for automatic annotation of the dental mandibular canal) ;** K213562	NobelClinician®, DTX Studio Implant (**Reference Device for the alignment of IOS to CBCT and guidance of surgery);** K163122	**Justification of Differences**
Mains Voltage, Frequency	115 VAC; 50 / 60 Hz	100 – 127VAC / 200 – 240VAC; 50 / 60 Hz	Not applicable	Not applicable	There has been no physical change to the X-Guide System Mains Voltage and Frequency. The X-Guide is not auto-ranging. It has always had a fixed nominal voltage. The reason for the apparent change is due to the update to the X-Guide System's IEC 60601-1-2 test report nomenclature. The updated ed 4.1 test report Unit Under Test section documents the Rated (Nominal) Voltage. The original ed 3.0 test report Unit Under Test section documents the range to which the device was subject during the test. The ed 4.1 test report's use of just the Nominal Voltage is more correct. 115 VAC is the only configuration sold in the United States of America. Therefore, only the 115 VAC unit is included in the subject device 510(k).
Input Power (VA)	1000VA	1500VA	Not applicable	Not applicable	The X-Guide System originally utilized an oversized transformer. This was updated in the IEC 60601-1-2 ed 4.1 test report.
Fusing Type / Rating	Circuit Breaker: 115VAC, 7A	Circuit Breaker: 100-127VAC, 10A	Not applicable	Not applicable	The X-Guide System has always had a fixed nominal voltage. The reason for the apparent change in the input voltage is due to the update to the X-Guide System's IEC 60601-1-2 test report nomenclature. The updated ed 4.1 test report Unit Under Test section documents the Rated (Nominal) Voltage. The original ed 3.0 test report Unit Under Test section documents the range that the device was subject to during the test. The ed 4.1 test report's use of just the Nominal Voltage is more correct. The change to the breaker is because the X-Guide System originally utilized an oversized circuit breaker. This was updated from 10 A to 7 A in the IEC 60601-1-2 ed 4.1 test report.

Degree of Protection Against Electrical Shock	Applied Part Type B	Applied Part Type B	Not applicable	Not applicable	No difference
Type of Protection Against Electrical Shock	Class I	Class I	Not applicable	Not applicable	No difference
Mode of Operation	Continuous	Continuous	Not applicable	Not applicable	No difference

Performance Testing

No performance standards have been established for Dental Stereotaxic Instruments under Section 514 of the Food, Drug and Cosmetic Act.

There are no changes to Biocompatibility, cleaning and sterilization, electrical safety, and electromagnetic compatibility. There are no changes to the physical X-Guide System itself or any of its components. The only change was to software.

Clinical Studies

No clinical studies were performed for the submission of this 510(k).

Non-Clinical Assessment

FDA Guidance Documents

X-Nav Technologies utilized the following FDA Guidance Documents in the preparation of this 510(k):

- Guidance for the Content of Premarket Submissions for Device Software Functions
- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions
- Good Machine Learning Practice for Medical Device Development: Guiding Principles

Software Development

Software development was conducted and documented in accordance to IEC 62304:2006+AMD1:2015.

Software and System Verification and Validation Testing

Software verification and validation testing were conducted and documented. The combined testing and analysis of results provides assurance that the device performs as intended.

Verification/Validation Type	Description
Machine Learning Outputs Validation	This validation test demonstrates that the machine learning software outputs correct segmentations and visualizations for the expected patient population.
Machine Learning Software Verification	This verification test demonstrates that the machine learning software meets specifications and requirements when integrated with the X-Guide System software, including the ability to automatically create a pan curve to fit the arch, register (superimpose) the IOS over the CT, and generate the X-Guide SurfiX.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971:2019 to review the following elements specific to the change:

- The risks associated with the use, usability and performance of the device
- the risks associated with and specific to the software design aspects of the device
- the risks associated with software functionality and software interaction with the user

Results were updated in the X-Guide Risk Analysis.

Conclusions

Based upon the information provided within this 510(k) Premarket Notification, we conclude that the X-Guide® Surgical Navigation System with integrated automatic image processing via machine learning software is substantially equivalent to the identified predicate device.