August 28, 2026

X-Nav Technologies, LLC
Kimberly Chan
Vice President of Regulatory Affairs and Quality Assurance
1555 Bustard Rd.
Suite 75 & 110
Lansdale, Pennsylvania 19446

Re: K253954
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: August 10, 2026
Received: August 10, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253954

Please provide the device trade name(s).

X-Guide Surgical Navigation System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

(As required by Section 807.92(c))

Date Prepared:	28 AUGUST 2026
Applicant:	X-Nav Technologies, LLC 1555 Bustard Road, Suite 75 & 110 Lansdale, PA. 19446
Contact Person:	Kimberly Chan Vice President of Regulatory Affairs and Quality Assurance Phone: 267-436-0414 regulatory@x-navtech.com
Device Trade / Proprietary Name:	X-Guide® Surgical Navigation System
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 (K232148)
Reference Devices:	X-Guide® Surgical Navigation System (K150222, K200662, K192579, K211071)

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 Handpiece) during surgical procedures.

The system is designed to assist in navigation of dental surgeries utilizing a Dental handpiece. These surgeries include performing endodontic access procedures, and delivering regulatory cleared dental implants. The addition of ToolTrace and Straight Cuts further supports dental implantation procedures by allowing the navigation of bone reduction (alveoloplasty).

This device consists of a Mobile Cart, equipped with a Monitor, Boom Arm, Navigation Assembly, optional Keyboard, Mouse and an Electronics Enclosure.

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

A Monitor, Keyboard, and Mouse serve as the main user interface for the surgeon.

The Boom Arm allows the operator to manipulate the Navigation Assembly position for optimal distance and alignment to patterns located with the surgical region (Surgi-Zone) for tracking purposes.

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 aid in 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-operative planning of the surgical procedure. The dental surgeon plans the surgical procedure in the X-Guide System Planning Software. A virtual implant or 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 intra-operative surgical stage, the system provides accurate guidance of the dental surgical instruments according to the pre-operative plan. Two primary, case-specific calibrations underpin the guidance system: Patient Tracker calibration and Handpiece calibration. Patient Tracker calibration is performed to determine the geometric relationship between the Patient Tracker and patient anatomy. Handpiece calibration is performed to determine the geometric relationship between the Handpiece Tracker or ToolTrace Handpiece Tracker and the tip of the surgical instrument. After calibration, as the dental surgeon moves the surgical instrument around the patient anatomy, 2D barcode tracking patterns on the Handpiece Tracker, ToolTrace 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 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.

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)

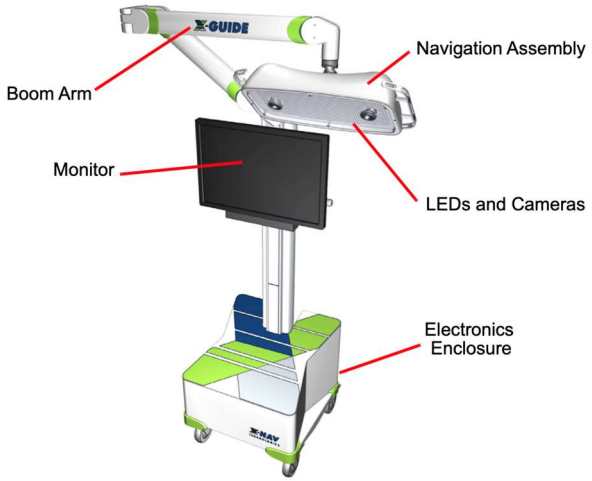
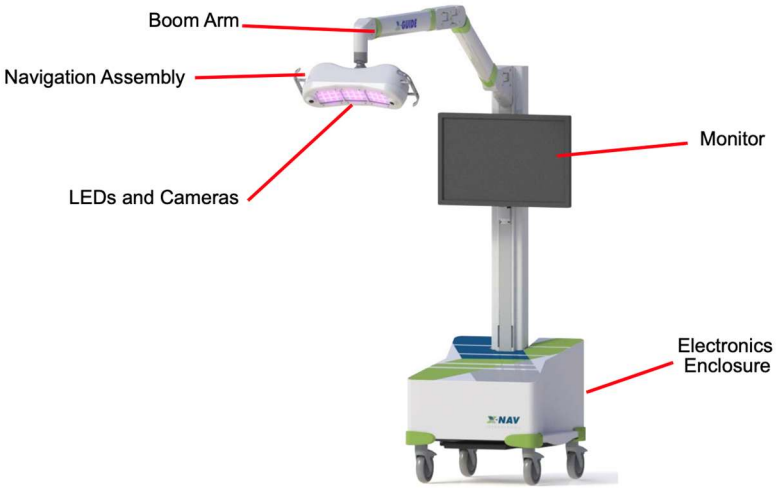


Figure 2: X-Guide® Surgical Navigation System (P011000)



Device Description

The 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 aids in 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.

Straight Cuts and ToolTrace

The proposed change is a software change with associated physical component changes, described below:

- Straight Cuts Planning and Navigation
- ToolTrace Calibration and Visualization during Navigation

Straight Cuts Planning

Straight Cuts Planning allows the use of a new planning tool during planning.

Straight Cuts Planning can be used to specify a straight cut between two defined points at a specific angle and depth. The planning screen allows for the practitioner to plan quadrilateral-shaped planning elements with a defined thickness.

Multiple straight cuts can be added in sequential fashion using the Extend button. These defined lines can be used to define cuts during surgery for bone reduction (alveoloplasty) using a cutting instrument.

The end user creates the plan using ‘control rods’ which define the endpoints of the cut. The endpoints are agnostic to which is the ‘start’ and which is the ‘end.’ Similarly to how single-trajectory points are currently defined in the X-Guide System, the Straight Cuts plan dimensions are controlled in the RxPanel, and affect the selected quadrilateral.

Straight Cuts Navigation

Straight Cuts Navigation allows the use of an alternative cutting guidance during navigated surgery. The trajectory visualization includes depth, position, and a cutting path to a user-defined endpoint.

The visualization for this feature is similar to that of the existing single-trajectory user interface during navigation. The interface shows pitch, roll, yaw, x, y, z, and depth of the handpiece relative to the planned quadrilateral.

- The depiction of pitch, roll, and yaw are identical between the single-trajectory interface and the Straight Cuts interface.
- Depth is depicted as a fillable bar which stretches across the entire path from Control Rod to Control Rod. The depth is a function of the location along the path.
- X, Y, and Z are still shown as the handpiece representation moving across the screen. Unlike single-trajectory navigation, the user is intended to follow the path from one Control Rod to the second Control Rod.

ToolTrace Calibration

ToolTrace is a new calibration method that can be used on cutting instruments with a variety of tip geometries (e.g., piezoelectric tips). The calibration involves identifying the tip location, cutting plane, and overall shape. These tool features are then displayed during navigated surgery to help the doctor align with the plan.

The process used to attach the Handpiece to the Handpiece Tracker is identical to the existing process for single-point burr ended handpieces. There are three components to calibration that must be performed: Tip Trace, Cutting Edge Trace, and Shape Trace.

ToolTrace Visualization during Navigation

An instrument calibrated using ToolTrace can be used in either a single-trajectory navigation, or in a Straight Cut navigation. The visualization appears differently compared to a shape-calibrated object, because the shape representation is customized to the user's specific tool.

Additional EDX Bone Screw Dimensions

To allow for tracking, physical components are sold with the X-Guide System, including Bone Screws. The Bone Screw is intended to be a transient, single use surgically invasive device. The Bone Screws are used to secure apparatus to the patient for mounting a tracking pattern, necessary for tracking patient positioning in space during surgical navigation. The Bone Screws are intended for use in adult and geriatric patient populations.

The EDX Bone Screws are a titanium alloy self-drilling screws which are tapered and vary in diameters. The already released EDX Bone Screws have diameters of 2.7 mm and 3.2 mm with thread lengths of 7mm and stud lengths of 4 mm, 8 mm, and 16 mm. The smaller diameter EDX Bone Screws are typically placed to secure the EDX Tracker Arm. Should the bone be too soft resulting in a loose Bone Screw, a large diameter “rescue” EDX Bone Screw can be placed.

All of the EDX Bone Screws and Caps are manufactured using a Ti6AL4V (Grade 5) alloy per ASTM F136 and adhere to the requirements of ASTM F543. There are no changes to this material.

The Bone Screws are intended to be removed from the patient at the conclusion of the surgical procedure. The Bone Screws are single use devices, sold in a non-sterile state and intended to be sterilized by the end user prior to use.

Proposed EDX Bone Screws

Individual Bone Screw Part Number	Individual Bone Screw Description	Packaged Part Number	Packaged Part Description
P011265	Bone Screw, EDX, 2.7 mm Dia X 5 mm Thread, 4 mm Stud	P012325	Bone Screw and Screw Cap, EDX - 2.7 Ø X 5 mm Thread, 4 mm Stud - 2ct
P011266	Bone Screw, EDX, 2.7 mm Dia X 5 mm Thread, 8 mm Stud	P012326	Bone Screw and Screw Cap, EDX - 2.7 Ø X 5 mm Thread, 8 mm Stud - 2ct
P011268	Bone Screw, EDX, 3.2 mm Dia X 5 mm Thread, 4 mm Stud	P012327	Bone Screw and Screw Cap, EDX - 3.2 Ø X 5 mm Thread, 4 mm Stud - 2ct
P011269	Bone Screw, EDX, 3.2 mm Dia X 5 mm Thread, 8 mm Stud	P012328	Bone Screw and Screw Cap, EDX - 3.2 Ø X 5 mm Thread, 8 mm Stud - 2ct
P011271	Bone Screw, EDX, 2.0 mm Dia X 7 mm Thread, 4 mm Stud	P012329	Bone Screw and Screw Cap, EDX - 2.0 Ø X 7 mm Thread, 4 mm Stud - 2ct
P011272	Bone Screw, EDX, 2.0 mm Dia X 7 mm Thread, 8 mm Stud	P012330	Bone Screw and Screw Cap, EDX - 2.0 Ø X 7 mm Thread, 8 mm Stud - 2ct
P011693	Bone Screw, EDX, 2.0 mm Dia X 11 mm Thread, 4 mm Stud	P012331	Bone Screw and Screw Cap, EDX - 2.0 Ø X 11 mm Thread, 4 mm Stud - 2ct
P011694	Bone Screw, EDX, 2.0 mm Dia X 11 mm Thread, 8 mm Stud	P012332	Bone Screw and Screw Cap, EDX - 2.0 Ø X 11 mm Thread, 8 mm Stud - 2ct
P011696	Bone Screw, EDX, 2.0 mm Dia X 15 mm Thread, 4 mm Stud	P012333	Bone Screw and Screw Cap, EDX - 2.0 Ø X 15 mm Thread, 4 mm Stud - 2ct
P011697	Bone Screw, EDX, 2.0 mm Dia X 15 mm Thread, 8 mm Stud	P012334	Bone Screw and Screw Cap, EDX - 2.0 Ø X 15 mm Thread, 8 mm Stud - 2ct
P012126	Bone Screw, EDX, 2.7 mm Dia X 11 mm Thread, 4 mm Stud	P012335	Bone Screw and Screw Cap, EDX - 2.7 Ø X 11 mm Thread, 4 mm Stud - 2ct
P012127	Bone Screw, EDX, 2.7 mm Dia X 11 mm Thread, 8 mm Stud	P012336	Bone Screw and Screw Cap, EDX - 2.7 Ø X 11 mm Thread, 8 mm Stud - 2ct
P012128	Bone Screw, EDX, 2.7 mm Dia X 15 mm Thread, 4 mm Stud	P012337	Bone Screw and Screw Cap, EDX - 2.7 Ø X 15 mm Thread, 4 mm Stud - 2ct
P012129	Bone Screw, EDX, 2.7 mm Dia X 15 mm Thread, 8 mm Stud	P012338	Bone Screw and Screw Cap, EDX - 2.7 Ø X 15 mm Thread, 8 mm Stud- 2ct

Proposed Labeling Changes – Removal of Contraindications

X-Nav is removing the contraindications for zygoma implants and pterygoid implants based on literature showing that the use of X-Guide and similar navigation systems with optical tracking provide similar surgical support and drilling accuracy as conventional implants when used for placement of these longer implant types.

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.

Intended 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.

Specifications

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

- Use Specifications
- Technology / Performance Characteristics
- Safety Features
- Components
- Bone Screw Specifics

Use Specifications

Use Spec	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K232148 & K200662	Navident (Predicate Device) ; K233563 & K210947	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 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.	Navident is a computerized dental navigational system intended to assist preoperative planning and to guide drilling in a patient jaw during implantation surgery and/or endodontic access procedures, using pre-acquired CT scan of the jaw. The device is intended for use by a qualified dental surgeon in the treatment of partially and fully edentulous jaws. The device is also intended for endodontic access procedures (i.e., access of calcified canals) where a CT scan is deemed appropriate as part of their treatment plan.	Differences in wording only.
Use Environment	Clinical Setting, Doctors Office	Clinical Setting, Doctors Office	Dental Clinic	Differences in wording only.
Contra-indications	• Not for use with patients less than 21 years of age. • Not for use with photosensitive epileptic patients. Patient sensitivity may be caused from the LEDs.	• Not for use with patients less than 21 years of age. • Not for use with photosensitive epileptic patients. Patient sensitivity may be caused from the LEDs. • Not for use with zygoma implants. • Not for use with pterygoid implants.	The use of Navident should be terminated when a stable coupling between the Navident optically-trackable marker and the patient's jaw cannot be achieved, or the accuracy check prior to the initiation of drill guidance has failed.	Removal of contraindications from Subject Device compared to Predicate X-Guide. Navident does not identify zygoma implants or pterygoid implants as contraindicated procedures. Subject of this 510(k).

Technology/Performance Characteristics

Technology / Performance Characteristics	X-Guide® (Subject Device)	X-Guide® (Predicate Device); K232148 & K200662	Navident (Predicate Device) ; K233563 & K210947	Justification of Differences
Tracking Technology	Stereo Cameras / LEDs / Pattern	Stereo Cameras / Pattern	Stereo Cameras / Checkerboard “Tags”	No difference between Subject Device and Predicate X-Guide. Navident utilizes checkerboard ‘tags’ instead of patterns, but the tracking concept is the same.
Calibration Frequency	Prior to each surgery	Prior to each surgery	Prior to each surgery	No difference.
Overall System Accuracy (RMS)	<1mm	<1mm	≤1.0mm	No difference.
Software	Navigational Guidance and Trajectory Planning	Navigational Guidance and Trajectory Planning	Navigational Guidance and Trajectory Planning	No difference.
Patient Calibration or Registration	X-Clip Edentulous Fiducials Anatomical Landmarks (X-Mark)	X-Clip Edentulous Fiducials Anatomical Landmarks (X-Mark)	NaviTray Edentulous Fiducials Anatomical Landmarks (Trace Register)	No difference between Subject Device and Predicate X-Guide. Navident has differences in wording only.
Planning Screens	Implant and Trajectory Planning Straight Cuts Planning	Implant and Trajectory Planning	Implant and Trajectory Planning ‘Saw Cut’ Planning	Addition of Straight Cuts Planning to Subject Device compared to Predicate X-Guide. Navident utilizes ‘Saw Cut’ Planning to place a quadrilateral shape, in the same way ToolTrace would be used to place a quadrilateral shape. Subject of this 510(k)
Handpiece Calibration	Contra-Angle Handpiece Calibration Straight Handpiece Calibration ToolTrace Calibration	Contra-Angle Handpiece Calibration Straight Handpiece Calibration	Contra-Angle Handpiece Calibration ‘Saw Cut’ Calibration with Piezoelectric Saw	Addition of ToolTrace Calibration method to Subject Device compared to Predicate X-Guide. Navident utilizes ‘Saw Cut’ Calibration to calibrate Piezo tools, in the same way ToolTrace would be used to calibrate Piezo tools. Subject of this 510(k)
Navigation Types Supported	Single-Trajectory Navigation (Target View) Straight Cuts Navigation	Single-Trajectory Navigation (Target View)	Single-Trajectory Navigation (Target View) Drilling Along a Planned Cut	Addition of Straight Cuts Navigation to Subject Device compared to Predicate X-Guide. Navident utilizes planned rectangles for Saw Cuts, but the Navigation utilizes a Target View. Subject of this 510(k)

Safety Features

Safety Features	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K232148 & K200662	Navident (Predicate Device) ; K233563 & K210947	Justification of Differences
Electrical Safety	IEC 60601-1:2005 Edition 3.2 AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006	IEC 60601-1:2005 Edition 3.2 AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006	IEC 60601- 1:2005 Edition 3.1 ANSI/AAMI ES60601-1:2005 / 2012 and C1:2009/ 2012 and A2:2010/ 2012	No difference between Subject Device and Predicate X-Guide. Minor edition differences between X-Guide and Navident.
Electromagnetic Compatibility	IEC 60601-1-2:2014+AMD1:2020	IEC 60601-1-2:2014+AMD1:2020	IEC 60601-1-2:2014 Edition 4.0.	No difference between Subject Device and Predicate X-Guide. Minor edition differences between X-Guide and Navident.
Biocompatibility	ISO 10993-1, -5, -10, -11, -12	ISO 10993-1, -5, -10, -11, -12	ISO 10993-1 series	No difference
Sterilization	Steam	Steam	Steam	No difference
Disinfectant (High Level)	3% Glutaraldehyde solution 0.55% Ortho-Phthalaldehyde (OPA)	3% Glutaraldehyde solution	Metricide, Sporox, or Cidex	Addition of OPA as an acceptable high level disinfectant to Subject Device compared to Predicate X-Guide. Navident utilizes Cidex, which is an OPA solution. Not the subject of this 510(k), but was deemed not a significant change due to the use of the same assessment procedure.
Ingress Protection	IP2X	IP2X	Not specified.	No difference

Components

Components	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K232148 & K200662	Navident (Predicate Device) ; K233563 & K210947	Justification of Differences
Patient Tracking Device	X-Corner Patient Tracker	X-Corner Patient Tracker	Jaw Tacker Head Tracker	No difference between Subject Device and Predicate X-Guide. Navident Trackers have checkerboard patterns on them with a similar concept to the X-Guide X-Corner.
Surgical Tool Tracking Device	X-Corner Handpiece Tracker X-Corner ToolTrace Handpiece Tracker	X-Corner Handpiece Tracker	Handpiece Tracker DrillTag	A second Handpiece Tracker with different patterns is added to the Subject Device so that the software can differentiate between a standard handpiece and a handpiece calibrated using ToolTrace. The tracking algorithm is identical between the two Handpiece Trackers, but uses a different 'expected' pattern for each. Subject of this 510(k). Navident also utilizes a checkerboard patterned Handpiece Tracker and DrillTag.
Edentulous Patient Tracking Attachment System	Edentulous Clip EDX Tracker Arms CLX Tracker Arms Bone Screw(s) EDX Bone Screw(s), Additional Dimensions	Edentulous Clip EDX Tracker Arms CLX Tracker Arms Bone Screw(s) EDX Bone Screw(s)	Bone Fixation Screw Kits	Additional dimensions to the Bone Screws, subject of this 510(k). Navident recommends third party bone fixation screws.
Patient Tracker Attachment Arms	Posterior Tracker Arm Anterior Tracker Arm	Posterior Tracker Arm Anterior Tracker Arm	Jaw Tracker T Jaw Tracker C Jaw Tracker B Jaw Tracker U Head Tracker	No difference between Subject Device and Predicate X-Guide. Navident Jaw Trackers allow for different configurations and orientations, similar to the X-Guide Tracker Arms
Affixation to Handpiece	Handpiece Connector Nut Handpiece Adaptor ToolTrace Handpiece Adaptor	Handpiece Connector Nut Handpiece Adaptor	Tag Adapter	Addition of the ToolTrace Handpiece Adaptor is added to the Subject Device. This part uses the same principle to rigidly affix the Handpiece Tracker Pattern to the doctor's handpiece, but which must be slightly larger to accommodate the thicker handpiece. Navident utilizes a Tag Adaptor to connect the Handpiece Tracker and DrillTag to handpieces and piezo tools.
Calibration Components	Calibration Disc Straight Calibration Bit ToolTrace Plate and Support Bar	Calibration Disc Straight Calibration Bit	Calibrator Tool	Addition of the ToolTrace Plate and Support Bar, which may be used to assist the doctor in the ToolTrace calibration process. Subject of this 510(k). Navident utilizes a Calibrator Tool which serves both as a Drill Bit Length Determination tool and an axis calibrator.
Registration Tool	Probe Tool	Probe Tool	Tracer-3 / Tracer-4	No difference
Drill Bit Length Determination	Go Plate	Go Plate	Calibrator Tool	No difference

X-NAV TECHNOLOGIES

Bone Screw Specifics

Components	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K232148 & K200662	Justification of Differences
Material	Titanium Ti-6AL-4V (Grade 5)	Titanium Ti-6AL-4V (Grade 5)	No difference
Screw Type	Self-Drilling Self-Tapping	Self-Drilling Self-Tapping	No difference
Manufacturing Method	Traditional (Subtractive)	Traditional (Subtractive)	No difference
Sterilization	Shipped non-sterile Moist heat sterilization at end user site	Shipped non-sterile Moist heat sterilization at end user site	No difference
Anatomical Sites	Mandible and Maxilla	Mandible and Maxilla	No difference
Diameter	2.0 mm (Classic and EDX) 2.7 mm (Classic and EDX) 3.2 mm (EDX only)	2.0 mm (Classic screws only) 2.7 mm (Classic and EDX) 3.2 mm (EDX only)	Adds the 2.0 mm diameter thread option to EDX screws, subject of this 510(k)
Thread Length	4 mm (Classic only) 6 mm (Classic only) 8 mm (Classic only) 10 mm (Classic only) 5 mm (EDX only) 7 mm (EDX only) 11 mm (EDX only) 15 mm (EDX only)	4 mm (Classic only) 6 mm (Classic only) 8 mm (Classic only) 10 mm (Classic only) 7 mm (EDX only)	Additional thread lengths for EDX screw type, subject of this 510(k)
Stud Length	4, 8, 16 mm	4, 8, 16 mm	No difference
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	No difference
Single Use	Yes	Yes	No difference
Shelf Life	None	None	No difference
Surface Casting	Anodizing	Anodizing	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. The components which were added to support ToolTrace are equivalent to the existing cleared X-Guide components, or could be justified. The bone screw components which are added are equivalent to the existing cleared X-Guide bone screws, and could be justified. Non-clinical testing supports the change to Indications for Use.

For the removal of contraindications for zygomatic and pterygoid implants, published clinical and *ex-vivo* literature was used.

Clinical Studies

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

Non-Clinical Assessment

Verification and Validation Testing

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
Straight Cuts End User Validation	This validation test demonstrates that the software usability for Straight Cuts was deemed acceptable by real end users.
ToolTrace End User Validation	This validation test demonstrates that the software usability for ToolTrace was deemed acceptable by real end users.
Straight Cuts Cadaver Study Accuracy Validation Test Report	This validation test demonstrates that the Straight Cuts software is accurate compared to freehand on cadavers.
ToolTrace Model Study Accuracy Validation	This validation test demonstrates that the ToolTrace software and hardware are accurate compared to freehand on models.
Straight Cuts Software Verification	This verification test demonstrates that the X-Guide System software meets specifications and requirements.
ToolTrace Software Verification	This verification test demonstrates that the X-Guide System software meets specifications and requirements.

Bench Testing

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
Bone Screw Mechnical Stability Test	This verification test demonstrates that the small length EDX Bone Screw thread is stable in a bone model, and deflection remains within requirements when attached to a weighted Tracker Arm.
ASTM F543 Annex A2	This verification test demonstrates that, for the worst case EDX Bone screw, the maximum insertion and removal torque is ≤50% of the screw torsional yield strength.

Supporting Literature

An ex-vivo (cadaver) study was performed at the system level and confirms comparable accuracy in placement of zygomatic implants to conventional length implants using the X-Guide® System.

Supporting literature from the secondary predicate device (NaviDent) was also used examining the accuracy of placement of pterygoid and zygomatic implants comparing free-hand placement and navigated placement in patients receiving full-arch restorative plans.

Study Title	Description
The Use of Dynamic Navigation for the Placement of Zygoma Implants: A Cadaver Study to Compare Accuracy	This study demonstrates that dental surgeons can effectively perform zygoma implant procedures with the X-Guide. The test method compared dynamically navigated zyogoma implant surgeries and freehanded zygoma implant surgeries in cadavers. The presurgical CBCT plan was compared to the navigated or freehanded trajectories in the post-operative CBCT. Both linear deviation and angular deviation were compared between the two experimental groups. The linear deviation and angular deviation in dynamically navigated zygoma implants were found to be better than freehand. The method assessing implant placement used in this study is well-established. It is the same as the method used in the predicate devices' 510(k) submissions, and involves a superimposition of the plan to the post-operative CT scan.
Navigated Flapless Placement of Zygomatic Implants: A Randomized Controlled Trial	This randomized controlled trial evaluated 20 patients receiving zygomatic implants using dynamic navigation with the NaviDent system, comparing a flapless approach to the conventional flapped technique. The flapless technique allowed implant placement under local anesthesia without raising a mucoperiosteal flap, relying on real-time navigation to guide implant positioning and sinus membrane elevation. Implant survival was high in both groups, with only one implant failure among 40 zygomatic implants placed. The failure rate is consistent with previously published systematic reviews of zygomatic implant failure rates. Rates of sinus complications and

	osseointegration were comparable between groups, and no postoperative neurosensory deficits were detected.
Comparative Evaluation of the Accuracy of Dynamic Navigation and Free Hand Methods During Zygomatic Implant Placement A Randomized Controlled Trial	The study provides published clinical evidence supports the use of dynamic navigation for zygomatic implant placement. In a randomized controlled clinical trial involving 40 zygomatic implants placed in patients with atrophic maxillae, dynamic navigation demonstrated significantly improved placement accuracy compared to freehand surgery at the implant entry point, apex, and angular position. Procedures were completed using the NaviDent system and dynamic navigation was compared to conventional flapped placement.
Accuracy of Dynamic Navigation Surgery in the Placement of Pterygoid Implants	The study provides published clinical evidence demonstrates successful use of implant navigation for pterygoid implant placement in a prospective randomized clinical trial involving 63 pterygoid implants in 39 patients using the NaviDent system and a split mouth protocol when available. The study concluded that pterygoid implant surgery is a predictable and successful treatment modality for placement of steep implant angulation and that dynamic navigation significantly improved placement accuracy compared to free-hand surgery, including accuracy relative to critical anatomical structures.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971 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
- The risks associated with the new length EDX Bone Screws
- The risks associated with navigating zygoma and pterygoid implants.

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 Straight Cuts and ToolTrace, alongside removed contraindications, is substantially equivalent to the identified predicate device.