February 1, 2022

X-Nav Technologies, LLC
Kimberly Chan
Regulatory Affairs Manager
1555 Bustard Road, Suite 75
Lansdale, Pennsylvania 19446

Re: K211701
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 5, 2022
Received: January 6, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211701

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.

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510(k) Summary – K211701

(As required by Section 807.92(c))

Date Prepared:	February 1, 2022
Applicant:	X-Nav Technologies, LLC 1555 Bustard Road, Suite 75 Lansdale, PA. 19446
Contact Person:	Kimberly Chan Regulatory Affairs Manager Phone: 267-436-0414 kimberly.chan@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 (K192579)
Reference Devices:	X-Guide® Surgical Navigation System (K150222, K200662)

Proposed Change to Indications

The indication statements are different from those of the predicate device.

Proposed 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.

Proposed 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.

The subject device is the same as the X-Guide® Surgical Navigation System cleared under K192579 (the predicate device) except for the changes to the indications for use. There is no change to the technological characteristics or components. There are no changes to the calibration process or navigation process. During dental implantation surgery for which the X-Guide System is already cleared, the dental surgeon performs several pilot drills to create a space for the implant in the bone prior to placement of the implant itself. This is no different than drilling a trajectory for endodontic access. The trajectory is established based on pre-planning in the software with a CBCT scan.

The differences in indication statements do not affect the substantial equivalence 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 Figure 1 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 implant process occurs in two stages. Stage 1 is the pre-planning of the surgical implantation procedure. The dental surgeon plans the surgical procedure in the X-Guide System Planning Software. 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 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.

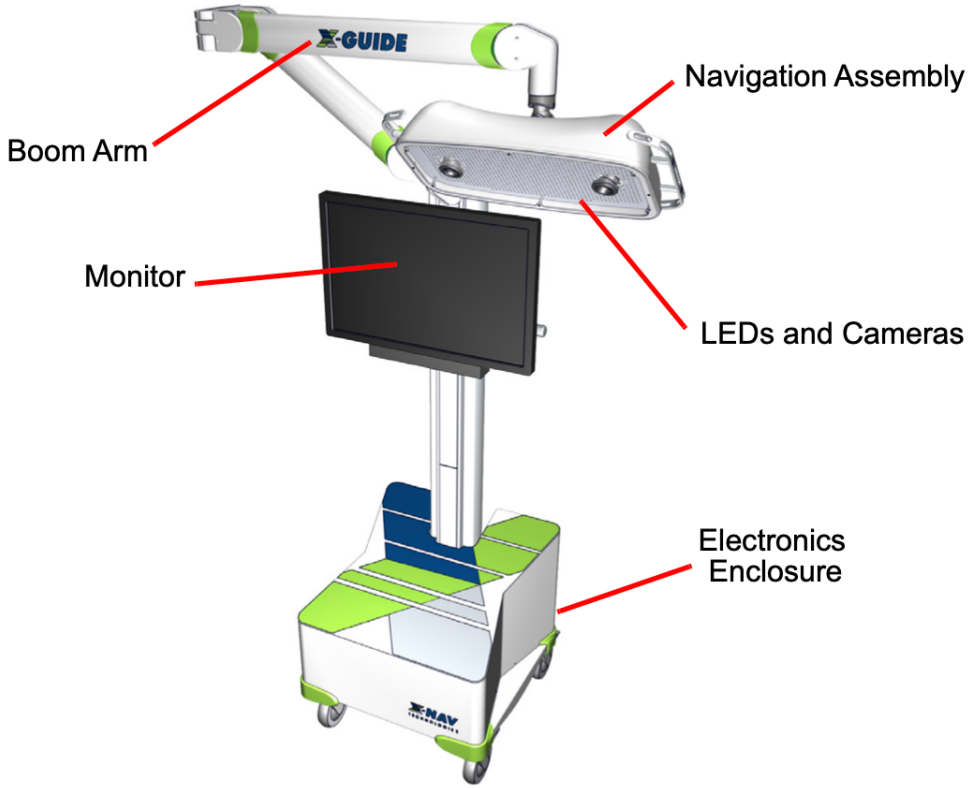
The relative motion of the dental handpiece and the patient anatomy, captured by the tracking hardware, is combined with patient-specific calibration data. This enables a 3D graphical representation of the handpiece to be animated and depicted in precise location and orientation relative to a 3D depiction 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



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.

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

X-NAV TECHNOLOGIES

Use Specifications

Use Specifications	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K192579	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. 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 inclusion of endodontic access procedures does not change the efficacy or safety of the X-Guide System. The X-Guide System is currently cleared to guide the dental surgeon to place implants. During dental implantation surgery, the dental surgeon drills pilot holes in the patient bone to make a space for the implant. The process for drilling a trajectory for endodontic access is no different. The independent studies listed in this 510(k) show that the X-Guide System is more accurate than freehand when used for this purpose. This 510(k) submission solely claims that the X-Guide System is safe and efficacious when used to create an endodontic access point. This 510(k) does not make claims regarding endodontic procedures beyond the creation of the access point.
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.	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 inclusion of endodontic access procedures does not change the efficacy or safety of the X-Guide System. The X-Guide System is currently cleared to guide the dental surgeon to place implants. During dental implantation surgery, the dental surgeon drills pilot holes in the patient bone to make a space for the implant. The process for drilling a trajectory for endodontic access is no different. The independent studies listed in this 510(k) show that the X-Guide System is more accurate than freehand when used for this purpose. This 510(k) submission solely claims that the X-Guide System is safe and efficacious when used to create an endodontic access point. This 510(k) does not make claims regarding endodontic procedures beyond the creation of the access point.

Use Environment	Clinical Setting, Doctors Office	Clinical Setting, Doctors Office	No difference

Technology/Performance Characteristics

Technology / Performance Characteristics	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K192579	Justification of Differences
Operating Temperature	10 - 35 deg C	10 - 35 deg C	No difference.
Operating Relative Humidity Altitude	30% - 90% non-condensing	30% - 90% non-condensing	No difference.
Transport Temperature Transport Humidity	500 hPa-1060hPa	500 hPa-1060hPa	No difference.
Optical Radiation	-20 - +60 deg C	-20 - +60 deg C	No difference.
Tracking Technology	10% - 95% non-condensing	10% - 95% non-condensing	No difference.
Calibration Frequency	LED, Risk Group 1 (minimal risk) per IEC 62471-1	LED, Risk Group 1 (minimal risk) per IEC 62471-1	No difference.
Overall System Accuracy (RMS) Alarms	Stereo Cameras / LEDs / Pattern	Stereo Cameras / LEDs / Pattern	No difference.
Alarms	Prior to each surgery	Prior to each surgery	No difference.
Monitor	<1mm	<1mm	No difference.
Communications	Audible, Visual	Audible, Visual	No difference.
Interface	LCD-TFT	LCD-TFT	No difference.
Software	Ethernet	Ethernet	No difference.
Fiducial Identification	Navigational Guidance and Implant Planning X-Clip \ Organic Fiducials \ Anatomical Landmarks	Navigational Guidance and Implant Planning X-Clip \ Organic Fiducials \ Anatomical Landmarks	No difference.
Edentulous Fiducial Registration	X-Mark Probe Tool	X-Mark Probe Tool	No difference.
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)	No difference.
Mounting	Mobile Cart	Mobile Cart	No difference.
Configuration Weight	130lbs. (58.97 kg)	130lbs. (58.97 kg)	No difference.

Safety Features

Safety Features	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K192579	Justification of Differences
Electrical Safety	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	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	No difference
Electromagnetic Compatibility	IEC 60601-1-2:2014 4th Edition	IEC 60601-1-2:2007 3rd Edition	No difference
Biocompatibility	Yes (ISO 10993-1, -5, -10, -11, -12)	Yes (ISO 10993-1, -5, -10, -11, -12)	No difference
Sterilization	Steam	Steam	No difference
Disinfectant (High Level)	3% Glutaraldehyde solution	3% Glutaraldehyde solution	No difference
Ingress Protection	IP2X	IP2X	No difference

Components

Components	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K192579 ; K200662	Justification of Differences
Bone Screw	Bone Screw(s)	Bone Screw(s)	No difference
CT / Patient Registration	X-Clip, Organic Fiducials, Anatomical Landmarks	X-Clip, Organic Fiducials, Anatomical Landmarks	No difference
Patient Tracking Device	X-Corner Patient Tracker	X-Corner Patient Tracker	No difference
Surgical Tool Tracking Device	X-Corner Handpiece Tracker	X-Corner Handpiece Tracker	No difference
Screwdriver	Yes	Yes	No difference
Edentulous Patient Tracking Attachment System	Edentulous Clip, EDX Tracker Arms, CLX Tracker Arms	Edentulous Clip, EDX Tracker Arms, CLX Tracker Arms	No difference
Registration Tool	Probe Tool	Probe Tool	No difference
Drill Bit Length Determination	Go Plate	Go Plate	No difference
Patient Tracker Attachment Arms	Posterior Tracker Arm; Anterior Tracker Arm	Posterior Tracker Arm; Anterior Tracker Arm	No difference

Energy

Energy	X-Guide® (Subject Device)	X-Guide® (Predicate Device) ; K192579	Justification of Differences
Mains Voltage, Frequency	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	No difference
Input Power (VA)	1500VA	1500VA	No difference
Fusing Type / Rating	Circuit Breaker: 100-127VAC, 10A	Circuit Breaker: 100-127VAC, 10A	No difference
Degree of Protection Against Electrical Shock	Applied Part Type B	Applied Part Type B	No difference
Type of Protection Against Electrical Shock	Class I	Class I	No difference
Mode of Operation	Continuous	Continuous	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, electromagnetic compatibility, and software, as there are no changes to the physical X-Guide System itself or any of its components.

Because there were no design changes to the X-Guide System, no verification or validation was performed. The rationale for this decision is rooted in the existence of independent studies that show the performance of the X-Guide System for endodontic access procedures when the system is used in its currently cleared configuration.

The inclusion of endodontic access procedures does not change the substantial equivalence of the X-Guide System.

The X-Guide System is currently cleared to guide the dental surgeon to place implants. During dental implantation surgery, the dental surgeon drills pilot holes in the patient bone to make a space for the implant. The process for drilling a trajectory for endodontic access is no different. The trajectory is established based on pre-planning in the software with a CBCT scan.

This 510(k) submission solely claims that the X-Guide System performance when used to create an endodontic access point. This 510(k) does not make claims regarding endodontic procedures beyond the creation of the access point.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, considering the modifications to the indications for use.

Risk Management includes FMEA analysis to review the following:

- risks associated with the use, usability and performance of the device (HFFMEA and Risk Analysis)

It was determined that there is no significant differences that required an update to the Risk Analysis. There are no new differences that raises any new issues of safety and effectiveness.

Clinical Studies

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

Assessment of Non-clinical Data

The use of the X-Guide Surgical Navigation System for endodontic access procedures did not create any new requirements, specifications, or design changes that required verification or validation. This conclusion is supported by an assessment of independent, non-clinical studies.

The studies were performed at the system level. They confirm the performance of the X-Guide® System. The studies are described in the table below.

Study Type	Description
Comparative cadaver study of 40 total human roots in 2 cadaver heads comparing X-Guide Dynamic Navigation versus Freehand Accuracy – Root Canal Access	This study demonstrates that endodontists can effectively perform endodontic access procedures with the X-Guide. The test method compared dynamically navigated endodontic surgeries and freehanded endodontic surgeries. 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 roots were found to be better than freehand. The method 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. This study's method deviated slightly from the predicate devices' 510(k). Instead of superimposing the pre-operative plan on the post-operative placed implant, the method in this study superimposed the plan to the post-operative *drilled trajectory*.
Comparative cadaver study of 60 total human single-rooted teeth mounted in 2 dry cadaver jaws comparing X-Guide Dynamic Navigation versus Freehand Accuracy – Apico Access	This study demonstrates that endodontists can effectively perform endodontic access procedures with the X-Guide using apico access. The test method compared dynamically navigated endodontic surgeries and freehanded endodontic surgeries. 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 roots were found to be better than freehand. The method 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. This study's method deviated slightly from the predicate devices' 510(k). Instead of superimposing the pre-operative plan on the post-operative placed implant, the method in this study superimposed the plan to the post-operative *drilled trajectory*.

Conclusions

In summary, using the X-Guide System for endodontic access procedures does not change the substantial equivalence of the device. The endodontic access procedures are no different than the existing X-Guide® Surgical Navigation System process for implants.

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.