February 3, 2020

X-Nav Technologies, LLC
Fred Cowdery
VP - Regulatory and Quality Compliance
1555 Bustard Road, Suite 75
Lansdale, Pennsylvania 19446

Re: K192579
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: PLV
Dated: November 4, 2019
Received: November 5, 2019

Dear Fred Cowdery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192579

Device Name
X-Guide® Surgical Navigation System

Indications for Use *(Describe)*
The X-Guide(R) Surgical Navigation System is a computerized navigational system intended to provide assistance in both the preoperative planning phase and the intra-operative surgical phase of dental implantation procedures.
The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments.

The device is intended for use for partially edentulous and edentulous adult and geriatric patients who require dental implants as part of their treatment plan.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K192579
(As required by Section 807.92)

Date Prepared: January 30, 2020

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

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

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

Device Name: Common / Usual: Surgical Navigation System

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

Regulatory Class: II

Product Code: PLV (Dental Stereotaxic Instrument)

Predicate Device Information

Category	Comments
Predicate Device:	X-Guide® Surgical Navigation System
Predicate Device Manufacturer:	X-Nav Technologies, LLC.
Predicate Device Common Name:	Surgical Navigation System
Predicate Device Premarket Notification#:	K150222
Predicate Device Classification:	21 CFR 872.4120 (Bone Cutting Instrument and Accessories)
Predicate Device Class & Product Code:	Class 2, PLV

Reference Device Information

Category	Comments
Reference Device:	StealthStation™ System with StealthStation™ Cranial Software
Reference Device Manufacturer:	Medtronic Navigation, Inc.
Reference Device Common Name:	Stereotaxic Instrument
Reference Device Premarket Notification#:	K153660
Reference Device Classification:	21 CFR 882.4560 (Stereotaxic Instrument)
Reference Device Class & Product Code:	Class II, HAW

Reference Device Information

Category	Comments
Reference Device:	Cranial Image Guided Surgery System
Reference Device Manufacturer:	BrainLab
Reference Device Common Name:	BrainLAB Cranial Image Guided Surgery System/ Instrument, Stereotaxic
Reference Device Premarket Notification#:	K092467
Reference Device Classification:	21 CFR 882.4560 (Stereotaxic Instrument)
Reference Device Class & Product Code:	Class II ,HAW

Indications for Use:

The X-Guide® Surgical Navigation System is a computerized navigational system intended to provide assistance in both the preoperative planning phase and the intra-operative surgical phase of dental implantation procedures.
The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments.

The device is intended for use for partially edentulous and edentulous adult and geriatric patients who need dental implants as part of their treatment plan.

Device Description:

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

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

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

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

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

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

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

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

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

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

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

Modifications made to the subject device are as follows:

1. An alternate method (X-Mark) is being proposed for registration of dentate and edentulous patients.
2. A new process is being proposed for correcting inaccurate patient registrations.
3. Two system hardware components, Probe Tool and Probe Tracker, are required to support these processes.

X- Mark Process (Proposed Patient Registration Change)

The X-Mark process is an alternate method of patient registration to the aforementioned cleared methods. Instead of placing and marking organic fiducials / Bone Screws (edentulous) or using an X-Clip (dentate), the doctor has the option to use existing anatomical landmarks as fiducials instead. These landmarks are manually marked in the X-Guide Software.

Once at least 3 anatomical landmarks are marked, the doctor registers the anatomical landmarks by touching them with the tip of a Probe Tool while the tracking system tracks the relationship between the Patient Tracker and Probe Tracker to complete the patient registration. This registration algorithm is identical to the existing cleared patient registration algorithm.

The doctor can choose teeth or anatomical landmarks as the fiducials.

Refinement Process

The Refinement process is a method for correcting inaccurate patient registrations.

This method involves "painting" an anatomical surface by moving the Probe Tool along the surface of a patients oral anatomy in order to generate a surface comprised of hundreds of surface points in the patient tracking coordinates.

The process then aligns the generated surface with the CBCT derived anatomical surface using the same cleared algorithms that are currently employed.

X-Mark Probe Tool / Probe Tracker

The X-Mark Probe Tool is used to register the locations of organic fiducials, bone screws, or anatomic landmarks within the patient's oral cavity as part of the Patient Registration process.

The Probe Tool is designed as a rigid structure for identifying locations within the patient oral cavity anatomy.

The Probe Tracker is geometrically / mechanically similar to the X-Corner Handpiece Tracker. Patterns on the Probe Tracker are tracked by the stereo cameras to indicate the X-Mark Probe Tool location, more specifically the Probe Tool Tip location, relative to patient anatomy.

Comparison to Predicate and Reference Devices:

As described in the tables below, the application device X-Guide® Surgical Navigation System (K192579) is substantially equivalent in intended use, design and physician use to the predicate device X-Guide® Surgical Navigation System (K150222). The application device is substantially equivalent in scientific technology to the reference device StealthStation™ System with StealthStation™ Cranial Software (K153660), specifically the cranial software.
The application device is also substantially equivalent in scientific technology to the reference device BrainLab Cranial Image Guided Device (K092467), supporting the method of patient registration using anatomical landmarks.

Table 1: Summary of Technological Characteristics Comparison

	Application Device	Primary Predicate Device	Reference Device	
Use Specifications	**X-Guide® Surgical Navigation System (K192579)**	**X-Guide® Surgical Navigation System (K150222)**	**StealthStation™ System with StealthStation™ Cranial Software (K153660)**	**Justification of Differences**
Indications for Use	The X-Guide® Surgical Navigation System is a computerized navigational system intended to provide assistance in both the preoperative planning phase and the intra-operative surgical phase of dental implantation procedures. The system provides software to preoperatively plan dental surgical procedures and provides navigational guidance of the surgical instruments. The device is intended for use for partially edentulous and edentulous adult and geriatric patients who need dental implants as part of their treatment plan.	The 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 StealthStation® System, with StealthStation® Cranial Software is intended as an aid for locating anatomical structures in either open or percutaneous procedures. The system is indicated for any medical condition in which reference to a rigid anatomical structure can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): • Cranial Biopsies • Deep Brain Stimulation (DBS) Lead Placement • Depth Electrode Placement • Tumor Resections • Craniotomies/Craniectomies • Skull Base Procedures • Transsphenoidal Procedures • Thalamotomies Pallidotomies • Pituitary Tumor Removal • CSF Leak Repair • Pediatric Ventricular Catheter Placement • General Ventricular Catheter Placement The user should consult the "Navigational Accuracy" section of the User Manual to assess if the accuracy of the system is suitable for their needs.	The Indications for Use of the application and Predicate Devices are identical. All of these devices are surgical navigation systems. The Application and Reference devices both have the ability to register patient anatomy using a combination of anatomical landmarks and software. As evidenced by the Reference Device, this capability has long been applied to such devices and raises no new questions for these types of devices.
Product Code	PLV	PLV	HAW	All three devices are stereotaxic instruments intended to be used for surgical navigation

	Application Device	Primary Predicate Device	Reference Device	
Technology / Performance Characteristics	**X-Guide® Surgical Navigation System (K192579)**	**X-Guide® Surgical Navigation System (K150222)**	**StealthStation™ System with StealthStation™ Cranial Software (K153660)**	**Justification of Differences**
Operating Temperature	10 - 35 deg C	10 - 35 deg C	Not Applicable	No difference.
Operating Relative Humidity	30% - 90% non-condensing	30% - 90% non-condensing	Not Applicable	No difference.
Altitude	500 hPa-1060hPa	500 hPA – 1060 hPA	Not Applicable	No difference.
Transport Temperature	-20 - +60 deg C	-20 - +60 deg C	Not Applicable	No difference.
Transport Humidity	10% - 95% non-condensing	10% - 95% non-condensing	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	No difference.
Tracking Technology	Stereo Cameras / LEDs / Patterns	Stereo Cameras / LEDs / Patterns	Stereo Cameras / LED Optical Markers / Sterile Sphere Or Electromagnetics (EM) AXIEM™	Tracking technology is equivalent for all three devices. The Reference Device offers an additional tracking technology option EM. The Application and Predicate devices do not require this additional tracking technology.
Calibration Frequency	Prior to each surgery	Prior to each surgery	Prior to each surgery	No difference.
Overall System Accuracy (RMS)	<1mm	<1 mm	<2 mm	No difference.
Alarms	Audible, Visual	Audible, Visual	Not Applicable	No difference.
Monitor	LCD-TFT	LCD-TFT	Not Applicable	No difference.
Communications Interface	Ethernet	Ethernet	Ethernet	No difference.
Software	Navigational Guidance and Implant Planning	Navigational Guidance and Implant Planning	Navigational Guidance and Surgical Planning	No Difference
Fiducial Identification	X-Clip \ Organic Fiducials \ Rigid Anatomical Landmarks	X-Clip \ Organic Fiducials	Rigid Anatomical Landmarks and StarFix™ Bone Anchor	Organic Fiducials are equivalent to Bone Screws. The Application and Reference Devices both provide similar means of Fiducial Identification. Similarly, the Application and Predicate Device each share common means (X-Clip or Organic Fiducials) of Fiducial Identification.
Edentulous Fiducial Registration Tool	X-Mark Probe Tool	Dental Handpiece with Burr	Registration Probes	No Difference - Equivalent to predicate and reference devices. X-Mark Probe Tool Tip provides increased rigidity and stability for more precise registration, minimizing accuracy errors during registration.

	Application Device	Primary Predicate Device	Reference Device	
Technology / Performance Characteristics	**X-Guide® Surgical Navigation System (K192579)**	**X-Guide® Surgical Navigation System (K150222)**	**StealthStation™ System with StealthStation™ Cranial Software (K153660)**	**Justification of Differences**
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	No difference.
Mounting Configuration	Mobile Cart	Mobile Cart	Not Applicable	No difference.
Weight	130lbs. (58.97 kg)	130lbs. (58.97 kg)	Not Applicable	No difference.

	Application Device	Primary Predicate Device	Reference Device	
Safety Features	**X-Guide® Surgical Navigation System (K192579)**	**X-Guide® Surgical Navigation System (K150222)**	**StealthStation™ System with StealthStation™ Cranial Software (K153660)**	**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 3.0 AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006 ISO15223-1:2012 BS EN ISO 14971:2012 IEC 62304:2006	Not Applicable	No difference - Product evaluated to latest revision of standards for compliance with EU Regulations
Electromagnetic Compatibility	IEC 60601-1-2:2014 4th Edition	IEC 60601-1-2:2007 3rd Edition	Not Applicable	No difference - Product evaluated to latest revision of standards for compliance with EU Regulations
Biocompatibility	Yes (ISO 10993-1, -5, -10, -11, -12)	Yes (ISO 10993-1, -5, -10, -11, -12)	Not Applicable	No difference.
Sterilization	Steam	Steam	Not Applicable	No difference.
Disinfectant (High-Level)	3% Glutaraldehyde solution	3% Glutaraldehyde solution	Not Applicable	No difference.
Ingress Protection	IP2X	IP2X	Not Applicable	No difference.

	Application Device	Primary Predicate Device	Reference Device	
Components	**X-Guide® Surgical Navigation System (K192579)**	**X-Guide® Surgical Navigation System (K150222)**	**StealthStation™ System with StealthStation™ Cranial Software (K153660)**	**Justification of Differences**
Bone Screw	Bone Screw	Bone Screw	StarFix™ Bone Anchor	No difference – Bone Screw and Bone Anchors both used to create fiducials to facilitate patient registration process.
CT / Patient Registration	X-Clip, Organic Fiducials, Anatomical Landmarks	X-Clip, Organic Fiducials	PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration	The Application and Reference Devices both utilize the application software to create a "translation map" between all points in the patient CT images and the corresponding points (Anatomical Landmarks) on the patient anatomy. After establishing this map, whenever the operator touches a point on the patient using a probing tool, the computer uses the map to identify the corresponding point on the images.
Patient Tracking Device	X-Corner Patient Tracker	X-Corner Patient Tracker	Localizer – Optical Markers or Electromagnetics	No difference.
Surgical Tool Tracking Device	X-Corner Handpiece Tracker	X-Corner Handpiece Tracker	Optical Markers	No difference.
Screwdriver	Yes	Yes	Not Applicable	No difference.
Edentulous Patient Tracking Attachment System	Edentulous Clip	Edentulous Clip	Not Applicable	No difference.
Drill Bit Length Determination	Go Plate	Go Button	Not Applicable	No change to part – Name change only
Patient Tracker Attachment Arms	Posterior Tracker Arm Anterior Tracker Arm	Posterior Tracker Arm Anterior Tracker Arm	Not Applicable	No difference.

	Application Device	Primary Predicate Device	Reference Device	
Energy	**X-Guide® Surgical Navigation System (K192579)**	**X-Guide® Surgical Navigation System (K150222)**	**StealthStation™ System with StealthStation™ Cranial Software (K153660)**	**Justification of Differences**
Mains Voltage, Frequency	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	Not Applicable	No difference.
Input Power (VA）	1500VA	1500VA	Not Applicable	No difference.
Fusing Type / Rating	Circuit Breaker: 100-127VAC, 10A	Circuit Breaker: 100-127VAC, 10A	Not Applicable	No difference.
Degree of Protection Against Electrical Shock	Applied Part Type B	Applied Part Type B	Not Applicable	No difference.
Type of Protection Against Electrical Shock	Class I	Class I	Not Applicable	No difference.
Mode of Operation	Continuous	Continuous	Not Applicable	No difference.

Performance Testing:

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

Biocompatibility Testing:
The biocompatibility evaluation for X-Guide® components was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included Cytotoxicity, Sensitization, Irritation, and System Toxicity.
The components of the X-Guide® are considered tissue contacting for a duration of less than 24 hours.
This testing demonstrates that the device materials will not cause a biocompatibility reaction when used as intended.

Cleaning and Sterilization Validation:
A representative sample of the re-usable components were tested to validate that the X-Guide® components can withstand the sterilization process and that acceptable sterility is achieved when using the recommended sterilization protocols. The sterilization validation testing was conducted according to ISO 17665-1:2006 and it validated that the reusable X-Guide® Surgical Navigation System components can be sterilized to reach an acceptable sterility assurance level.

Electrical Safety and Electromagnetic Compatibility (EMC):
Comprehensive performance testing has been conducted on the X-Guide® Surgical Navigation System in accordance with the latest recognized industry standards, by an accredited NRTL. Product Safety was evaluated for compliance with IEC 60601- 1:2005 Edition 3.1 ANSI/AAMI ES60601-1:2005 / 2012 and C1:2009/ 2012 and A2:2010/ 2012 (Consolidated Text) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. Electromagnetic Compatibility was assessed for compliance with IEC 60601-1-2:2014 Edition 4.0. A risk-based approach was used to assess product compliance for Safety and EMC.

Software and System Verification and Validation Testing:

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

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

Software Development and Testing was performed per IEC 62304:2006 Medical Device Software – Software Lifecycle Processes, FDA Guidance for the Content of Premarket. Submissions for Software Contained in Medical Devices and FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff.

Risk Management was performed in compliance with ISO 14971:2012 and includes FMEA analysis to review the following:

- risks associated with the use, usability and performance of the device (HFFMEA and Risk Analysis)
- the risks associated with and specific to the design aspects of the device (Risk Analysis)
- the risks associated with software functionality and software interaction with the user (Risk Analysis)
- Risks associated with biocompatibility, cleaning and sterilization

Non-Clinical Testing:

X-Mark and Refinement process verification and validation testing has been performed at the system level. The testing is described in the table below.

Verification / Validation Type	Description
Simulated Use (End User Validation)	This usability validation test demonstrates that the intended end users of X-Guide can perform critical tasks with the X-Mark and Refinement processes for the intended uses in the expected use environments.
Total System Accuracy	Quantify Position Accuracy of X-Mark and Refinement processes using ASTM 2554-18 with additional testing to the PAF process in comparison to predicate system accuracy.
Probe Tool / Probe Tracker Calibration	Confirm accuracy and repeatability of calibrations for both devices.
Accuracy (Dentate Patients)	Comparison in accuracy of Patient Registration between X-Clip and X-Mark processes
Accuracy (Edentulous Patients)	Comparison in accuracy of Patient Registration between X-Mark and Organic Fiducial registration.
Reusable components Sterilization Life Expectancy	Intended to confirm number of sterilization cycles the Probe Tracker can withstand without compromising pattern integrity.
End User Validation of User Requirements for Probe Tool and Probe Tracker	Confirm Probe tool and Probe Tracker function as intended and meet user needs.
Probe Tool Tip Mechanical Properties	Confirms the X-Mark Probe Tool tip radius within the pivot hole of the Go Plate meets the functional requirement for tip radius.

Nonclinical Comparisons to Predicate Device in this Submission

The following tests performed to establish substantial equivalence for the Probe Tool and Probe Tracker to the Dental Handpiece with a burr

- Probe Tip Accuracy and Deflection
    - The interaction between the X-Mark probe tip and Go-Plate (P008641) during calibration is crucial in controlling accuracy. By controlling the tip design, the lateral movement of the tip in the Go Plate can be limited. Dental handpiece burrs can wear over time making this lateral movement hard to control/quantify.
    - The length of the X-Mark Probe Tool has been kept small to minimize bending of the probe tip, as well as allow easier access to the posterior region of the mouth. The tip is also welded to the handle, so no motion can occur at the attachment point. In a dental handpiece, however, there will be slop in the chuck due to tolerances inherent in handpiece designs.

- Comparison of materials' material safety data sheets (MSDS)
    - Probe Tool Tip vs. Dental Burr
        - Dental burrs are made from tungsten carbide. Tungsten carbide is extremely hard which allows the bur to maintain a sharp cutting edge. Due to the hardness, the drills are stiffer than stainless steel but more prone to fracturing.
        - The Probe Tool Tip is made of 316L Stainless Steel allowing the user to push on the probe laterally without the risk of fracturing the probe tip. 316L Stainless Steel is a commonly used material for surgical instruments.
- Simulated clinical use validation (simulated processes using cadavers)
  Surgeons separately performed patient registrations using both the X-Mark and Refinement processes on Dentate and Edentulous patients. Qualitative and Quantitative validation data and usability endpoints were captured and recorded for each of the tests.

Clinical Testing:

No clinical studies were performed as appropriate verification and validation of the application device was achieved from the results of bench performance testing, biocompatibility evaluation, sterilization, and cleaning evaluation

Conclusions:

The X-Guide® Surgical Navigation System has been shown through comparison and testing to be substantially equivalent to the identified predicate and referenced devices when used as intended.