May 21, 2020

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

Re: K200662
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: April 20, 2020
Received: April 24, 2020

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)*
K200662

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 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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

**Date Prepared:** May 20, 2020

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

**Contact Person:**
Fred Cowdery
Vice President – Regulatory and Quality Compliance
Ph 267.436.0414
Email: fred.cowdery@x-navtech.com

**Device Trade/Proprietary Name:** X-Guide® Surgical Navigation System

**Device Name: Common / Usual:** Surgical Navigation System

**ClassificationName:** 21 CFR 872.4120 (Bone Cutting Instrument and Accessories)

**Regulatory Class:** II

**Product Code:** PLV

**Primary Predicate Device:** X-Guide® Surgical Navigation System (K150222)

**Reference Device:** KLS Martin Individual Patient Solutions (K163579)

**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 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 implantation 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 X-Guide® Surgical Navigation System is currently cleared (K150222) with Bone Screws which are intended to affix an Edentulous Clip to an edentulous patients anatomy. The attachment of the Edentulous clip is necessary to attach tracking patterns to facilitate the navigation and tracking process, and is calibrated to the patient anatomy and CT.

As an alternative, the proposed EDX Bone Screws and EDX Nut may be used to secure tracking patterns to edentulous patient anatomy.

The proposed EDX Bone Screws are a titanium alloy self-drilling screws which are tapered and vary in 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. In addition to the dimensional design changes, the screws have been modified with an M5 threading to accept the EDX Nut. The addition of M5 threading to the top half of the Bone Screw is necessary to secure the tracking patterns to the patient.

The 2.7 mm 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 (3.2 mm diameter) can be placed.

All of the EDX Bone Screws and EDX Bone Nuts are manufactured using a Ti6AL4V (Grade 5) alloy per ASTM F136 and adhere to the requirements of ASTM F543.

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

The body of the proposed EDX Tracker Arms are made from a stainless steel, which is a harder material providing more stability / rigidity in the Tracker Arm. A passivation coating is added to prevent oxidation of the during steam sterilization.

The EDX Tracker Arms include a spike intended to added stability in EDX Tracker Arm registration.

The body of the proposed EDX Tracker Arms are contoured in a variety of geometric shapes intended to minimize interferences with patient soft tissue by positioning on the Mandible and Maxilla in the posterior and anterior positions of the oral cavity.

The EDX Tracker Arms are distributed in a non-sterile state, and intended to be sterilized by the end user prior to use.

**Proposed Components:**

| X-Nav Part Number | Description |
|---|---|
| P010303 | Bone Screw, Length: 4mm; Diameter: 2.7mm |
| P010304 | Bone Screw, Length: 8mm; Diameter: 2.7mm |
| P010305 | Bone Screw, Length: 16mm; Diameter: 2.7mm |
| P010306 | Bone Screw, Length: 4mm; Diameter: 3.2mm |
| P010307 | Bone Screw, Length: 8mm; Diameter: 3.2mm |
| P010308 | Bone Screw, Length: 16mm; Diameter: 3.2mm |
| P010869 | Tracker Arm Assembly; EDX, Posterior Upper Right |
| P010870 | Tracker Arm Assembly; EDX, Posterior Upper Left |
| P010871 | Tracker Arm Assembly; EDX, Anterior Upper Right |
| P010872 | Tracker Arm Assembly; EDX, Anterior Upper Left |
| P010873 | Tracker Arm Assembly; EDX, Posterior Lower Right |
| P010874 | Tracker Arm Assembly; EDX, Posterior Lower Left |
| P010875 | Tracker Arm Assembly; EDX, Anterior Lower Right |
| P010876 | Tracker Arm Assembly; EDX, Anterior Lower Left |
| P010660 | Bone Screw Nut, EDX |

**Comparison to Predicate and Reference Devices:**
As described in the tables below, the application device X-Guide® Surgical Navigation System 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 KLS Martin Drill Free® MMF Screw.

**Table 1: Summary of Technological Characteristics Comparison**

| | Application Device | Primary Predicate Device | Reference Device | |
|---|---|---|---|---|
| **Use Specifications** | **X-Guide® Surgical Navigation System** | **X-Guide® Surgical Navigation System (K150222)** | **KLS Martin Individual Patient Solutions (K163579)** | **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. | KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction. | The proposed device and Predicate device share the same intended use. Although the reference device has a different intended use, it was chosen to show there are cleared devices of the same diameter. |
| Product Code | PLV | PLV | DZL | |

| | Application Device | Primary Predicate Device | Reference Device | |
|---|---|---|---|---|
| **Technology / Performance Characteristics - Bone Screws** | **X-Guide® Surgical Navigation System (K200662)** | **X-Guide® Surgical Navigation System (K150222)** | **KLS Martin Individual Patient Solutions (K163579)** | **Justification of Differences** |
| Material | Titanium Ti-6AL-4V (Grade 5) | Titanium Ti-6AL-4V (Grade 5) | Titanium Ti-6AL-4V | No Difference |
| Screw Type | Self- Drilling<br>Self-Tapping | Self- Drilling<br>Self-Tapping | Self- Drilling<br>Self-Tapping | No Difference |
| Manufacturing Method | Traditional (Subtractive) | Traditional (Subtractive) | Traditional (Subtractive) | No Difference |
| Sterilization | Non-sterile (Steam) | Non-sterile (Steam) | Non-sterile (Steam) | No Difference |
| Anatomical Sites | Mandible and Maxilla | Mandible and Maxilla | Mandible and Maxilla | No Difference |
| Diameter | 2.7 mm, 3.2 mm | 2.0 mm, 2.7 mm | 2.0 mm – 3.2mm | No Difference |
| Thread Length | 7 mm | 4, 6, 8, 10, mm | 5 mm – 22 mm | Application Device Thread Length is within range of Predicate and Reference devices. |
| Thread Pitch | 2.7mm diameter: 1.20 mm<br>3.2mm diameter: 1.23 mm | 2.0mm Diameter: 0.80 mm<br>2.7 mm Diameter: 1.20 mm | Documentation does not list thread pitch | 2.7mm pitch is based off of predicate. 3.2 pitch is derived from Table A5.2 listed in ASME F543-17, Metallic Medical Bone Screws |
| Stud (Shaft) Length | 4,8 16 mm | N/A | N/A | Stud offsets EDX Tracker Arm from bone and tissue, allowing the tracker arm to be clamped between the EDX Nut and Bone Screw providing increased mounting stability. Predicate and reference devices clamp Edentulous Clip or Bone Plate directly to the bone which may have curvatures. |
| Biocompatibility | Biocompatible in accordance with ISO 10993-1 | Biocompatible in accordance with ISO 10993-1 | Biocompatible in accordance with ISO 10993-1 | No Difference |
| Single Use | Yes | Yes | Yes | No Difference |
| Shelf Life | None | None | Unknown | No Difference |
| Surface Casting | Anodizing | Anodizing | Anodizing | No Difference |

| | Application Device (K200662) | Primary Predicate Device | |
|---|---|---|---|
| **Technology / Performance Characteristics - Tracker Arm** | **X-Guide® Surgical Navigation System (EDX Tracker Arms)** | **X-Guide® Surgical Navigation System (K150222) (Predicate Tracker Arms)** | **Justification of Differences** |
| Material | Stainless Steel (316L) | Aluminum 6061-T6 (Grade 5), 316L, | Stainless Steel has stronger material properties and is therefore a more rigid material than Aluminum. |
| Manufacturing Method | Traditional (Subtractive) | Traditional (Subtractive) | No Difference |
| Sterilization | Non-sterile (Steam) | Non-sterile (Steam) | No Difference |
| Anatomical Sites | Mandible and Maxilla (8 Versions) | Mandible and Maxilla (3 Versions) | Additional arm shapes to avoid interference with patient soft tissue and surgical instruments. |
| Spikes | Spike is between mounting holes on tracker arm to provide stability | Spikes are underneath E-Clip to provide stability | No Difference |
| Attachment Method | Clamped between EDX Nut and EDX Bone Screw | Tracker arm is attached to E-clip via tracker arm screw. E-Clip is clamped between bone screw and patient bone. | EDX mounting technique provides improved mounting stability, allowing the tracker arm to be clamped between the EDX Nut and bone screw and offset from soft tissue. |
| Stud (Shaft) Length | 4, 8, 16 mm | Not Applicable | EDX Bone Screw shaft offsets Tracker Arm above bone and tissue, allowing the tracker arm to be clamped between the EDX Nut and bone screw. |
| Biocompatibility | Biocompatible in accordance with ISO 10993-1 | Biocompatible in accordance with ISO 10993-1 | No Difference |
| Single Use | No | No | No Difference |
| Shelf Life | None | None | Similar |
| Surface Casting | Passivation | Anodizing/Passivation | Predicate Device is Anodized. Application Device is passivated. Both methods are acceptable industry standards to prevent corrosion. |

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)
- Risks associated with biocompatibility, cleaning and sterilization

Additional warning information was added to the product labeling to mitigate any residual risks.

**Performance Testing - Non-Clinical:**

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

1. Mechanical Properties:
   The predicate devices Bone Screws were tested in accordance with ASTM F543-17. A review of the test results and comparison of the mechanical properties of the predicate device Bone Screws and the EDX Bone Screws confirms the subject device (EDX Bone Screws) are substantially equivalent to the predicate device Bone Screws.
   Additional mechanical testing was conducted on the subject device to assess comparative deflection and stability of the EDX assembly under load conditions.

2. Biocompatibility:
   Per FDA Guidance document 1811, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", section IV.A, biocompatibility testing is not necessary 'if the sponsor is able to document the use of a particular material in a legally-marketed predicate device or a legally-marketed device with comparable tissue exposure, and is able to explain why manufacturing is not expected to adversely impact biocompatibility."
   The EDS Bone Screws, EDX Bone Screw Nut, and EDX Tracker Arms were deemed to be equivalent in material, process, and tissue contact to the predicate device. Therefore, this submission is relying upon the results of Biocompatibility Testing (Cytotoxicity, Sensitization, and Irritation) conducted on our predicate device (K150222) to demonstrate biocompatibility compliance for the proposed components.

3. Sterilization Testing:
   The EDX Bone Screws are considered geometrically similar to the predicate X-Guide® Surgical Navigation System Bone Screws, which were successfully tested and determined to meet a sterility assurance level (SAL) of ≤10-6 using the biological indicator (BI) overkill method.
   Therefore, this submission is relying upon the results of cleaning and sterilization validation conducted per ISO 17665-1 and FDA Reprocessing Guidance Document to demonstrate compliance for the subject components.

**Performance Testing - Clinical Testing:**

Clinical testing was not necessary for the substantial equivalence determination.

**Substantial Equivalence Conclusion:**

Substantial equivalence between the predicate and reference devices and the proposed EDX Bone Screw, EDX Tracker Arms, and EDX Bone Screw Nut has been demonstrated throughout this submission by performance analysis and bench testing, comparison of intended clinical application, and similarity in materials.

This submission has demonstrated that differences in materials, geometry, or application methods between the proposed EDX components and the predicate and reference devices do not raise any new issues of substantial equivalence.

Additionally, the proposed changes within this Special 510(k) are substantially equivalent to the predicate device in the following:

- Same indications for Use
- Sterilized in accordance with validated methods
- Biocompatibility