February 22, 2022

Navigate Surgical Technologies Inc.
% Pamela Buckman
Regulatory/Clinical Consultant
Pamela Buckman, MSN
921 Calle Verde
Martinez, California 94553

Re: K213392
Trade/Device Name: INLIANT® 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 23, 2021
Received: November 26, 2021

Dear Pamela Buckman:

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,

Andrew I. Steen
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)*
K213392

Device Name
INLIANT® Surgical Navigation System

Indications for Use *(Describe)*

The INLIANT Surgical Navigation System (INLIANT) is a computerized navigational system intended to provide assistance in both pre-operative planning and the intra-operative surgical phase of dental implantation procedures. INLIANT provides software to pre-operatively plan dental implantation procedures and provides navigational guidance of surgical instruments.

INLIANT is intended for use for partially edentulous adult 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.

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

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510(k) Summary
K213392

General Information

Date Prepared: February 22, 2022

Proprietary Name: INLIANT® Surgical Navigation System

Common Name: Dental Stereotaxic Instrument

Classification Name: Bone Cutting Instrument and Accessories

Regulation: 21 CFR 872.4120

Regulatory Class: Class II

FDA Panel: Dental

Product Code: PLV

Applicant:
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Indication for Use: The INLIANT Surgical Navigation System (INLIANT) is a computerized navigational system intended to provide assistance in both the pre-operative planning and the intra-operative surgical phase of dental implantation procedures. INLIANT provides software to pre-operatively plan dental implantation procedures and provides navigational guidance of surgical instruments.

INLIANT is intended for use for partially edentulous adult patients who require dental implants as part of their treatment plan.

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

Device Description: INLIANT is a dynamic surgical navigation system designed to allow a clinician to plan a dental procedure and then provide accurate guidance in real-time as to the location of dental surgical tool's drill tip relative to the patient's anatomy and planned implant position during the dental surgical procedure.

INLIANT includes a stand-alone cart which provides mobility and structural support for the computer, monitor and the camera which consists of two high resolution optical image sensors and lens assemblies. The system also includes the handpiece (model WI-75 LED G cleared under K080939), Patient Trackers and Fiducial Kit.

Operation of INLIANT is based on optical tracking. Stereoscopic images of the markers on the Patient Tracker and a handpiece are captured by the camera above the surgical site. INLIANT software processes the captured images to determine the location and orientation of the hand piece with respect to the Patient Tracker which is rigidly attached to the patient. The position of the handpiece, drill and the planned implant position is overlaid on existing CBCT scans of the patient's jaw and displayed to the clinician.

Comparison of Technological Characteristics: The INLIANT Surgical Navigation System (INLIANT) and the predicate device, X-Guide Surgical Navigation System (X-Guide), provide three-dimensional (3D) orientation and position of surgical tools displayed on a computer monitor in real-time within a patient's 3D imaging data set (CT images). Both systems utilize a dynamic computer-assisted surgery system based on optical motion tracking technology which tracks the position of the surgical tool to a sub-millimeter accuracy relative to the position of the patient throughout dental implant osteotomy preparation. Neither device is intended to replace human assessment, but to provide objective information relating to the positioning and alignment of the surgical tools in reference to the patient's anatomy.

INLIANT and the predicate device share many characteristics. These characteristics are provided in the following table:

Characteristic	INLIANT (subject)	X- Guide (predicate)	Comparison/Conclusion
Indications for Use	INLIANT is a computerized navigational system intended to provide assistance in both the pre-operative planning and the intra-operative surgical phase of dental implantation procedures. INLIANT provides software to pre-operatively plan dental implantation procedures and provides navigational guidance of surgical instruments. The device is intended for use for partially edentulous adult patients who require 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 pre-operative planning phase and the intra-operative surgical phase of dental implantation procedures. The system provides software to pre-operatively 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.	The INLIANT is not intended for fully edentulous patients or geriatric patients as indicated in the predicate. The exclusion of fully edentulous patients and geriatric patients does not impact substantial equivalence as the INLIANT intended for use on a subset of the patient population of the predicate, partially edentulous patients.
Main Functions	CT-based implant placement planning. Presentation of position, angle, and depth indicators when drilling in the jaw.	CT-based implant placement planning. Presentation of position, angle and depth indicators when drilling in the jaw.	Identical

Characteristic	INLIANT (subject)	X- Guide (predicate)	Comparison/Conclusion
Performance Characteristics			
Accuracy at the Drill Tip	≤1.0mm	≤1.0mm	Identical
Presentation Update Rate	Real time	Real time	Identical
Technological Characteristics			
Input Imaging Modality	Computerized Tomography	Computerized Tomography	Identical
Dynamic Object Pose Measurement Technology	Stereoscopic triangulation of marker patterns.	Stereoscopic triangulation of illuminated checker-board patterns (X-Corners).	Equivalent
Hand piece tracking	Optical marker patterns on the hand piece.	An optically marked tube-like attachment to the back of the hand piece.	Equivalent
Jaw Tracking Attachment	INLIANT Fiducial is a nonconductive plastic piece with embedded radiopaque spheres. Molded thermoplastic is inserted into the INLIANT Fiducial tray and placed on available dentition to form the Stent. During surgery, Patient Tracker (optically marked) is connected to the Fiducial	U- shaped "X-clip" with a molded thermoplastic insert, mounted on the available dentition. During surgery, a metallic arm holding an optically marked metal cylinder is connected to it.	Equivalent. In both systems, a thermoplastic part is molded to the surface of the jaw to provide a coupling to the teeth with the optically tracked object rigidly connected to the molded part.
Patient to CT Image Registration	Automatic, using small radiopaque spheres embedded in a uniquely shaped, nonconductive plastic piece.	Manual, using small fiducial spheres embedded in the X-clip and a jaw tracker calibration process.	Equivalent. In both systems, fiducial objects of known shapes are used to obtain a registration mapping between the patient jaw

			and the CT image.
Jaw Attachment Calibration	Not needed	Needed prior to each operation. Different procedures depending on the type of attachment.	Equivalent. INLIANT markers on Patient Tracker are permanent and pre- calibrated.
Characteristic	INLIANT (subject)	X- Guide (predicate)	Comparison/Conclusion
Drill length measurement	Drill length measurement is done by touching a point on the Patient Tracker. Drill length measurement is followed by "anatomy check" to confirm system's accuracy. Drill length measurement is done after every drill change.	Initial hand piece calibration is done using hand piece calibration disc (a special optically marked tool) while drill bit length calculation is done by touching a point on a Go-plate (another optically marked tool). Drill length measurement is followed by "anatomy check" to confirm system's accuracy. Drill length measurement is done after every drill change.	Equivalent. INLIANT markers on hand piece are permanent and pre-calibrated. Patient Tracker is used to perform the drill length measurement.
Mount Configuration	Mobile cart	Mobile cart	Identical
Presentation of Navigation Guidance	3D graphics presentation of drill position, angle and depth relative to planned placement.	3D graphics presentation of drill position, angle and depth relative to planned placement.	Identical
llumination of tracking targets	Visible light emitted by existing dental light or operatory lighting.	Visible light emitted by LED panel	Equivalent

Non-Clinical Testing: Device testing was conducted to evaluate conformance to product specifications and applicable standards. Conclusions drawn from these non-clinical tests demonstrate that INLIANT is substantially equivalent to the predicate device. The following standards were applied:

- Guidance on Premarket Notification [510(k)] Submissions for Medical Devices
- EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes
- EN ISO 14971:2012 Medical devices. Application of risk management to medical devices
- IEC 62304:2006 Medical device software. Software life cycle processes
- IEC 62366:2008 Medical devices. Application of usability engineering to medical devices
- IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6 Medical electrical equipment Part 1-6: General requirements for safety -- Collateral Standard: Usability

Bench Testing:

- Software Validation and documentation for software of moderate level of concern was provided per the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." All software verification/validation passed.
- Cybersecurity Evaluation per the FDA Guidance Document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."
- Cleaning and disinfection validations were performed in accordance with FDA Guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. All testing passed.
- Steam Sterilization Validation was conducted in accordance with ANSI/AAMI/ISO 17665-1, ISO 17665-2, and ANSI/AAMI ST79. All testing passed.
- Gamma radiation validation per ISO 11137-1 and -2 and shelf life/package integrity validation per ISO 11607-1, ASTM F2096, and ASTM F88.
- Biocompatibility assessment and testing was conducted per FDA Guidance Document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." The patient contacting components of the device passed cytotoxicity, sensitization, intracutaneous irritation, and oral mucosa irritation biocompatibility testing.
- Performance testing was conducted to evaluate the tolerance analysis, latency, positional and tracking accuracy per ASTM F2554, tracker environmental conditions, drill length measurement accuracy, system verification, and design validation. The acceptance criteria were met.

Usability Testing: A usability validation testing included 8 participants from 8 clinics. The study was conducted at Navigate Surgical Technologies Inc, in a simulated dental clinic operatory. Observational data were collected during the testing and participants completed a questionnaire. Analysis of the data demonstrated that the INLIANT System's user interface performed as expected for the intended users, uses, and use environments, and that no further modification to the user interface was necessary.

Animal testing: No animal testing was conducted or included in support of the INLIANT submission.

Clinical Performance: Clinical testing was performed. The purpose of the clinical study was to confirm that the corrective actions identified in the Root Cause Analysis successfully reduce the angular inaccuracy of dental implants placed using the INLIANT device in a clinical setting. Specifically, it is designed to confirm that the INLIANT device is equivalent to the predicate device by measuring the angular and lateral deviations between the planned and placed implant positions. The study employed a confirmatory, single-clinic, non-randomized study of the INLIANT device to aid dental implant placement. A total of 23 implants were placed among 22 adult subjects. The subject population were dental clinic patients, male and female adults age 22 years and older in good general health in need of 1-2 implants with each tooth having at least two adjacent zero mobility teeth in the same arch on which surgery was to be performed. Four investigators used INLIANT to place the dental implants. Deviations between the planned implant positions and placed implant positions were measured. The study endpoints were evaluated by the lateral (coronal and apical) and angular deviations between the pre-planned implant positions and actual implant positions were measured by registering pre-operative and post-operative CBCT scans in a common reference. Patients were followed up 2-4 weeks post-surgery.

The primary study research question inquired as to the probability of having all three of the lateral and angulation measurements be statistically less than their respective noninferiority upper equivalence bounds that preserve 80% of the advantage of the predicate device compared to freehand. These bounds are 3.903˚ for angular deviation, 0.8661 mm for coronal lateral deviation, and 1.145 mm for apical lateral deviation. Results for all three types of deviations support the conclusion that the deviations are significantly different than their respective upper equivalence bound, and non-inferior to the predicate. There were no adverse events reported.

CONCLUSION

The summary includes the conclusions drawn from the nonclinical and clinical tests demonstrate that the device is substantially equivalent to the predicate device.