July 28, 2020

Neocis Inc.
Thomas E. Claiborne, Ph.D.
Regulatory Affairs Manager
2800 Biscayne Blvd. Suite 600
Miami, Florida 33137

Re: K200805
Trade/Device Name: Neocis Guidance System (NGS) with Patient Splints
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: April 28, 2020
Received: April 29, 2020

Dear Thomas E. Claiborne:

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)*
K200805

Device Name
Neocis Guidance System (NGS) with Patient Splints

Indications for Use *(Describe)*
The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments. The NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

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

I. Submitter

Neocis Inc.
2800 Biscayne Blvd.
Suite 600
Miami, FL 33137
Tel: 1-855-9NEOCIS

Contact Person: Thomas E. Claiborne, Ph.D., Regulatory Affairs Manager
Date Prepared: July 27, 2020

II. Device

Trade Name:	Neocis Guidance System (NGS) with Patient Splints
Common Name:	Dental Stereotaxic Instrument
Classification Name:	Bone cutting instrument and accessories (21 CFR 872.4120)
Classification:	Class II
Product Code:	PLV

III. Predicate Devices

- X-Guide Surgical Navigation System (K150222)

IV. Reference Devices

- Neocis Chairside Splint (K173402)
- Dentsply Sirona Cerec Guides (K190059)
- Stryker Mandibular Fracture and Reconstruction Fixation System, Bone Fixation Screws (K014263)

V. Indications for Use

The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments. The NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

VI. Device Description

The Neocis Guidance System (NGS) (K161399) is a dental stereotaxic instrument (Product Code PLV) and a powered surgical device for bone cutting (21 CFR 872.4120). The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides precise and accurate navigational guidance of surgical instruments, with regard to pre-operative planning in dental implantation procedures. The system allows the user to plan the surgery virtually in software using a cone beam computed tomography (CBCT) scan of the patient, and the plan is used by a guidance system to provide physical, visual, and audible feedback to the surgeon during the implant site preparation. The holds and guides a standard FDA-cleared powered bone cutting instrument.

The implant process occurs in two phases. First, the dental surgeon plans the surgical procedure with the planning software. A virtual implant is placed at the desired location in the CT scan, allowing the dental surgeon to avoid interfering with critical anatomical structures during implant surgery. Second, when the implant plan is optimally positioned, the NGS provides accurate guidance of the dental surgical instruments according to the pre-operative plan. The NGS can be used for flapless dental implant procedures, which is a type of minimally invasive surgical approach. The NGS provides haptic feedback to the surgeon by constraining the motion of the bone cutting instrument to the plan. This allows the surgeon to feel resistance to attempts at motions that may deviate from the plan.

The patient tracking portion of the NGS is comprised of linkages from the patient to the NGS, which include the Chairside Patient Splint (CPS) (K173402), the End Effector (EE) and the Patient Tracker (PT). The Patient Splint is attached to the contralateral side of the patient's mouth over stable teeth. The CPS is placed on the patient using on-label dental materials (K182776) prior to the presurgical CBCT scan. A Fiducial Array (FA) with radio-opaque fiducial markers is placed on the CPS prior to the CBCT scan so the virtual plan can be related to the physical space of the system using the markers. The PT is an electromechanical feedback system that is connected to the CPS on the patient, which relays information to the control software in order to track patient movement. If patient movement occurs during the surgical procedure, the system will respond by altering the prescribed surgical cutting angle, position, and depth to accommodate the patient movement, which will maintain the accuracy of the osteotomy.

The subject of this submission is our Edentulous Patient Splint (EPS). The EPS is affixed to the anterior mandible or maxilla using standard bone screws. Like the CPS, the EPS serves as rigid connection to the patient for robotic tracking of the patient during the procedure. The EPS is intended for use in partially edentulous and fully edentulous adult patients.

VII. Comparison of Technological Characteristics

This submission includes changes to the indications for use and a new patient splint for use in partially edentulous and fully edentulous patients. There are no changes to the NGS hardware or software in this submission. Since the NGS (K161399) was previously found to be substantially equivalent to K150222, we refer to our prior clearance for a full technological comparison. We have selected K150222 again as a predicate device because we now have technology that allows us to match its performance requirements for fully edentulous patients, which is the focus of this submission. The differences introduced by this modification are detailed in Table 1: Comparison of technological characteristics to the predicates
below.

Table 1: Comparison of technological characteristics to the predicates

Technological Characteristics	**NGS with Patient Splints** ***Subject Device***	**X-Guide Surgical Navigation System** ***Predicate Device (K150222)***	**Reference Device-CPS K173402**	**Reference Device-Sleeves K190059**	**Reference Device-Screws K014263**	**SE Analysis**
Indications for Use (IFU)	The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments. The NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.	The X-Guide(R) 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 require dental implants as part of their treatment plan.	The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides navigational guidance of the surgical instruments.	N/A	N/A	Added condition and patient population from predicate.

Technological Characteristics	NGS with Patient Splints *Subject Device*	X-Guide Surgical Navigation System *Predicate Device (K150222)*	Reference Device-CPS K173402	Reference Device-Sleeves K190059	Reference Device-Screws K014263	SE Analysis
Contraindications	The Neocis Guidance System is not intended for use with patients that have insufficient bone to retain a Neocis Edentulous Patient Splint (EPS) rigidly throughout a surgical procedure. The EPS should not be affixed to patients that exhibit: •Patients with insufficient bone quality •Patients with a history of jaw or TMJ pain	Medical conditions which contraindicate the use of X-Guide and its associated applications include any medical conditions which may contraindicate the medical procedure itself. Only for those where dental implants are appropriate & patient is healthy. • Not for use with patients less than 21 years of age. • Not for use with photosensitive epileptic patients. Patient sensitivity may be caused from the LEDs.	The Neocis Guidance System is not intended for use with patients that have insufficient bone to retain a Neocis Edentulous Patient Splint (EPS) rigidly throughout a surgical procedure. The EPS should not be affixed to patients that exhibit: Patients with insufficient bone quality Patients with a history of jaw or TMJ pain Patients with allergies to acrylates	N/A	N/A	Adjusted for EPS. Acrylic-like dental materials are not used with the EPS. Similar to X-Guide.
Patient Contacting Materials	• Ixef®-HC-1022 • Stainless Steel • Titanium Alloy	• Stainless Steel • Titanium Alloy	IXEF	Stainless Steel	Titanium	Addition of predicate materials
NGS Power Supply	120VAC/60 Hz	120VAC/60Hz	Same as the subject device	N/A	N/A	Same
Type of Protection against Electric Shock	Class I Equipment	Class I Equipment	Same as the subject device	N/A	N/A	Same

Technological Characteristics	**NGS with Patient Splints *Subject Device***	**X-Guide Surgical Navigation System *Predicate Device (K150222)***	**Reference Device-CPS K173402**	**Reference Device-Sleeves K190059**	**Reference Device-Screws K014263**	**SE Analysis**
Equipment Suitable for use in the presence of Flammable Mixtures?	No	No	N Same as the subject device /A	N/A	N/A	Same
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Same as the subject device	N/A	N/A	Same
Electromagnetic Disturbances	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Same as the subject device	N/A	N/A	Same
Ingress Protection	IPX0	IPX2	Same as the subject device	N/A	N/A	The X-Guide has a higher IPX rating. NGS is 0 because of our draping.
Mode of Operation	Continuous Operation	Continuous Operation	Same as the subject device	N/A	N/A	Same
System Lateral Accuracy	RMS < 1 mm	RMS < 1 mm	Same as the subject device	N/A	N/A	Same

Technological Characteristics	NGS with Patient Splints *Subject Device*	X-Guide Surgical Navigation System *Predicate Device (K150222)*	Reference Device-CPS K173402	Reference Device-Sleeves K190059	Reference Device-Screws K014263	SE Analysis
System Depth Accuracy	RMS < 1 mm	RMS < 1 mm	Same as the subject device	N/A	N/A	Same
System Angular Accuracy	RMS < 6.0°	---	Same as the subject device	N/A	N/A	Same
CT Scan Quality Requirements	0.3 mm Voxel, 0.3 mm Slice Thickness, Matrix 512 x 512, Full 13 cm 21 sec, Multi 2 DICOM format.	---	Same as the subject device	N/A	N/A	NGS has tighter tolerances than X-Guide.
F/T Sensor Force Measurement Range	+/- 30 N	N/A	Same as the subject device	N/A	N/A	The X-Guide does not use F/T sensors
F/T Sensor Torque Measurement Ra nge	+/- 2 Nm	N/A	Same as the subject device	N/A	N/A	The X-Guide does not use F/T sensors
F/T Sensor Single Axis Force Overload Limit	200 N	N/A	Same as the subject device	N/A	N/A	The X-Guide does not use F/T sensors
F/T Sensor Single Axis Torque Overload Limit	20 Nm	N/A	Same as the subject device	N/A	N/A	The X-Guide does not use F/T sensors
Upper limit specification for Guidance Arm Translation Speed	1.25 m/s	N/A	Same as the subject device	N/A	N/A	The X-Guide does not have a guidance arm.
Storage Requirements	Store powered at Room Temperature (68°F to 76°F or 20°C to 24.4°C) and standard ambient humidity (5% to 95%) in a dust free, clean environment.	-20 to 60 °C, 10-95% humidity	Same as the subject device	N/A	N/A	Same

Technological Characteristics	**NGS with Patient Splints *Subject Device***	**X-Guide Surgical Navigation System *Predicate Device (K150222)***	**Reference Device-CPS K173402**	**Reference Device-Sleeves K190059**	**Reference Device-Screws K014263**	**SE Analysis**
Patient Tracking	Physical linkage to patient via Patient Tracker and Kinematic Mount connected to: • EPS, or • CPS (K173402)	Stereo-LED Optical tracking of: • E-clip • Tracker Arm • X-Corner Patient Tracker	Same as the subject device with CPS	N/A	N/A	Addition of EPS to NGS workflow, which is SE to the X-Guide E-clip.
Affixation of tracking technology to patient	• EPS with sleeves and bone screws • CPS with dental materials (K182776)	Metal strip (stainless steel or titanium bone fixation plate) and titanium bone screws	Dental Materials	Sleeves	Screws and screwdriver	Same methods for subject device and predicate device using reference devices for implementation
Patient attachment removal	• CPS can be removed manually or by powered cutting tool • EPS is removed by unscrewing the bone screws	The metal strip is removed by unscrewing the bone screws	Standard dental techniques	N/A	Use of screwdriver	Addition of predicate removal techniques and reference device implementation
Fiducials	Fiducial Array (FA) attached to splint	X-clip fiducial attached to patient's teeth or organic fiducials in patient's bone	Same as the Subject Device	N/A	N/A	NGS Fiducial is not patient contacting
Kinematic mount	Integrated into the splint	E-Clip tracker arm slot integrated into metal strip (bone plate)	KM as separate part	N/A	N/A	Similar implementation
Biocompatibility	Yes (ISO 10993-1, -5, -10, -12)	Yes (ISO 10993-1, -5, -10, -11,-12)	Yes (ISO 10993-1, -5, -10, -12)	Yes (ISO 10993-1, -5, -10, -12)	Yes (ISO 10993-1, -5, -10, -12)	Same

Technological Characteristics	NGS with Patient Splints *Subject Device*	X-Guide Surgical Navigation System *Predicate Device (K150222)*	Reference Device-CPS K173402	Reference Device-Sleeves K190059	Reference Device-Screws K014263	SE Analysis
Sterilization	Steam (ISO 17665-1)	Steam (ISO 17665-1)	Steam (ISO 17665-1)	Steam (ISO 17665-1)	Steam (ISO 17665-1)	Same
Dental Drill Motor and Hand Piece	• Held by NGS guidance arm • Aseptico Drill Motor (Model No. AEU-7000LNE-70V) (K030163) • Anthogyr Mont Blanc handpiece (Aseptico Model No. AHP-85MBFO-CX) (K070084)	Not specified, handheld	Same as the Subject Device	N/A	N/A	Aseptico cleared for use with NGS under K191605, NGS guidance arm SE under K161399
Planning Software	• Neocis Planning Software Application v1.2 (K161399), or • Neocis Planning Software Application for 3rd Party PCs v1.8.1 (K191363)	Implant Planning Software XOS	Same as the Subject Device	N/A	N/A	SE under K161399
Software Level of Concern	Moderate	Moderate	Same as the Subject Device	N/A	N/A	Same

VIII. Performance Testing

The subject of this 510(k) was a modification to the indications for use and the addition of a splint for use in edentulous patients. There are no changes to the NGS in this submission. As such, NGS performance testing was not repeated.

Prior Performance Testing from K173402:

Chairside splint verification and validation testing from K173402 is described below in **Table 2**.

Table 2: Summary of component and system verification and validation

Verification / Validation Type	Description
Simulated Use (End User Validation)	Run through of typical splint affixation cases using typodonts, performed by Surgeons.
Total System Accuracy	The Total System was evaluated for accuracy via simulated use with a typodont as simulation of a patient with three osteotomies per typodont in four locations (Upper Right / Upper Left / Lower Right / Lower Left).
Patient Tracker and Splint Mounting Verifications	Evaluating the effect of 2x Patient Tracker weight as total downward force on a standard splint mounted on a typodont per the IFU. In addition, evaluation of kinematic mount repeatability and patient anatomy accommodation analysis.

Prior Performance Testing from K161399:

Biocompatibility Testing

The biocompatibility evaluation for NGS components was conducted in accordance with

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff Document issued on: June 16, 2016
ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

The components of the NGS are considered tissue/dentin contacting for a duration of less than 24 hours.

Electrical Safety

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

Software and System Verification and Validation

ANSI AAMI IEC 62304:2006 Medical device software - Software life cycle processes
Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005

Software testing summary is in table 3.

Table 3: Summary of all software and system verification and validation

Verification / Validation Type	Description
Simulated Use	Run through of Typical Use Case

Verification / Validation Type	Description
Boundary Condition	Testing of all potential boundary parameters in the Application Software
Registration	Testing of registration process
Case File Contents	Simulated use testing of features associated with saving / loading Cases
Error Case Injection	Simulating all error messages and pop-ups.
CT Scan Verification	Verification of the resolution and validity of CT Scans
Control SW Boundary Condition Testing	Testing the mechanical boundaries of the Control Software and Guidance Arm.
Control Software Gravity Calibration Verification	Verifying that the Gravity Calibration is effective over multiple start-up / shut down cycles
Work Volume and Floor Grid Verification	Verifying the design and functionality of the Work Volume and Floor Grid features in the application software.
Accuracy Verification: Patient Tracker	The Patient Tracker was evaluated for accuracy per ASTM F2554.
Guidance Arm Accuracy / Repeatability	The positional accuracy of the Guidance Arm was evaluated by collecting 27 data points in spaces within two work volumes (54 total points) against a calibrated CMM.
Communication Rate Verification	Force-Torque (F/T) Sensor to Control Software, Patient Tracker to Control Software, Guidance Arm to Control Software and communication between Application Software and Control Software rates were evaluated for appropriate speed.
End User Calibration Verification	Dimensional analysis and verification of Calibration Materials (Calibration Drill Bit and Calibration End Effector Divot)

Verification / Validation Type	Description
F/T Sensor Verification	Guidance Arm speed limit testing and drift / idle F/T Sensor verification, intended to evaluate safety mitigations for Guidance Arm motion.
Start-Up / Shutdown Process Verification	Qualitative evaluation of all start-up / shutdown steps performed in a simulated clinical environment.
Start-Up Joint Position Identification	Verification to ensure system integrity of Guidance Arm in case any joint motion that may have occurred while system was not powered.
User Emergency Safety Verification	Evaluation of time required for a Guidance Arm emergency shutdown, and emergency disconnection of the patient.
Guidance Arm Adjustment to Patient Motion	Simulation of Patient Tracker motion while system is in Drill Mode, and drill bit is in simulated bone block
Work Volume Verification	Assessment of physical design and cable management throughout available work volumes.
Speed Trap Verification	Evaluation of the Guidance Arm and Patient Tracker speed trap safety mitigations.
End User Validation of User Requirements	Validation of User Requirements as they pertain to NGS Design and Development, and Software Lifecycle Design and Development, performed by End User in simulated environment.
End User Validation of User Requirements for Splint Application and Removal	An addendum to the NGS End User Validation to repeat validation steps associated with changes made to the design and instructions for the use of the NGS Splint.
End User Validation of User Requirements for Changes made to Patient Tracker End Effector	An addendum to the NGS End User Validation to repeat validation steps associated with changes made to the design, and procedural steps associated with the Patient Tracker End Effector

VERIFICATION

EPS Bench Testing

Sterilization Validation

ANSI AAMI ISO 17665-1:2006/(R)2013 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

Rigidly mounted EPS deflection measurement:

Internal protocol to measure the deflection error introduced by the weight of our patient tracker.

Kinematic Mount Repeatability measurement:

Internal protocol to measure the repeatability of connection to the kinematic features of the device.

Total System Accuracy

The full system is used to perform a simulated clinical procedure on a typodont to measure the system accuracy.

PRE-CLINICAL VALIDATION

EPS Cadaver Testing

Human cadaver heads (n=2) were used to test EPS affixation and removal. One surgeon experienced with the NGS performed the procedures. Two splints (1 upper, 1 lower) were tested per surgeon. The Surgeon used bone screws to secure the splints. They attached the Patient Tracker to the EPS and moved the head around. Rigidity of splint affixation was checked qualitatively. Surgeons were asked qualitative performance questions about the device.

CLINICAL VALIDATION

IDE Study G190282

We conducted a prospective two-center (private practice) IDE study that was not randomized or controlled. The study was conducted in accordance with Good Clinical Practice (GCP) requirements. Informed consent was obtained from each patient and IRB approval was obtained prior to starting the study. It was feasibility style design to test the performance and usability of the device. We had two clinical investigators, one per site. Each site had 5 adult patients (10 total). Patients were male and female and representative of the dental implant surgery population. Patients were fully chronically edentulous or partially edentulous and edentulated prior to surgery. Study sample size was based on the total number of dental implants placed using the study device (n=67). Endpoints included usability, safety, and effectiveness. Participating surgeons were fully licensed to practice dental implant surgery and were trained on use of the study device prior to starting the study. Patients were followed for two-weeks postop to examine wound site healing. There were no adverse events observed or reported. There were no usability concerns identified. We examined implant location accuracy using a before and after analysis of CT data showing the location and position of the implant in the preop plan versus postop CT. All implants met system specifications for accuracy. Patient risks have been mitigated by design. No new clinical risks were identified in comparison to the predicate and our preop risk assessment.

IX. Conclusion

There are no technological changes to the NGS in this submission. The changes in this submission are limited to the indications for use and the new edentulous patient splint. Changes to the indications for use specify the same condition and patient population as the X-Guide predicate. The EPS represents an operative guidance technique substantially equivalent to predicate. Our performance testing demonstrates substantially equivalent performance of the EPS as compared to the predicate. The bench and clinical testing are sufficient to demonstrate that the EPS is substantially equivalent to the predicate.