DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 22, 2016

Neocis Inc.
Alon Mozes, Ph.D.
CEO and Co-Founder
2800 Biscayne Blvd Suite 600
Miami, Florida 33137

Re: K161399
Trade/Device Name: Neocis Guidance System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: November 30, 2016
Received: December 1, 2016

Dear Alon Mozes:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161399

Device Name
Neocis Guidance System

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.

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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Section 7. 510(k) Summary

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

Contact Person: Alon Mozes, Ph.D.
2800 Biscayne Blvd.
Suite 600
Miami, FL 33137
Tel: (305) 409-2819

Date Prepared: December 20, 2016

Trade Name: Neocis Guidance System (NGS)

Common Name: Dental Stereotaxic Instrument

Classification Name: Bone cutting instrument and accessories (21 CFR 872.4120)

Classification: Class II

Product Code: PLV

Predicate Device: X-Guide® Surgical Navigation System (K150222) as primary predicate, IGI System (K023424) as reference device

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.

Device Description:
The Neocis Guidance System (NGS) is a stereotaxic medical device that guides surgeons during dental implant surgery (see **Table 1** below for significant physical and performance characteristics details). The system allows the user to plan the surgery virtually in software using a CT 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 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.

Physical guidance is provided via the Guidance Arm. The Guidance Arm grips a standard dental drill from the back end, allowing the surgeon to grip the drill as normal. The Guidance Arm does not move unless the surgeon applies a manual force to the drill. The Guidance Arm will constrain the surgeon to drill according to the prescribed surgical plan, preventing deviation. The surgeon is constantly in control of the drilling.

Visual guidance is provided by 3D graphics and 2D cross sections that indicate the position and orientation of the drill in relation to the pre-operative plan and scan. The visual feedback is updated in real-time so any relative motion between the dental handpiece and the patient properly update the visualization.

The patient tracking portion of the NGS is comprised of the Patient Splint and the Patient Tracker. The Patient Splint is attached to the contralateral side of the patient's mouth. The Patient Splint is placed on the patient prior to the CT scan. A fiducial array with fiducial markers is placed on the Patient Splint prior to the CT scan so the virtual plan can be related to the physical space of the system. The Patient Tracker is a mechanical feedback system that is connected to the Patient Splint 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 and position to accommodate the patient movement, which will maintain the accuracy of the drill placement.

Several steps are required for calibration and measurement during the procedure. The drill is calibrated using the Calibration Drill Bit inserted into a precise position on the Patient Tracker. During the surgery, each drill bit must be measured with the Depth Gauge to determine the proper length of the bit. These measurements complete the loop so the entire NGS is accurate to the tip of the drill.

The NGS is a supporting device, providing additional information and guidance to the decision-making process during the surgical procedure. It is not intended to replace the surgeon's judgment. The final clinical decisions 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.

Technological Characteristic	**Neocis Guidance System**
Supply Voltage	120 V
Phases	1
Type of Current	AC
Rated Frequency (Hz)	60 Hz
Rated Power Input (VA)	600 VA
Types and Ratings of external accessible fuses	5.0 A for 240 V
Type of Protection against Electric Shock	Class I Equipment

Degree of Protection against Electric Shock	Type BF
Equipment Suitable for use in the presence of Flammable Mixtures?	No
Mode of Operation	Continuous Operation
System Lateral Accuracy	RMS < 1 mm
System Depth Accuracy	RMS < 1 mm
System Angular Accuracy	RMS < 6.0°
CT Scan Quality Requirements	0.3 mm Voxel, 0.3 mm Slice Thickness, Matrix 512x512, Full 13cm 21 sec, Multi 2 DICOM format.
F/T Sensor Force Measurement Range	+/- 30 N
F/T Sensor Torque Measurement Range	+/- 2 Nm
F/T Sensor Single Axis Force Overload Limit	200 N
F/T Sensor Single Axis Torque Overload Limit	20 Nm
Upper limit specification for Guidance Arm Translation Speed	1.25 m/s
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.

Table 1: Significant physical and performance characteristics of the NGS

Comparison of Technological Characteristics:

Both the subject and predicate systems provide accurate guidance of surgical tools and implantable devices through the use of computer-aided navigation. This guidance is achieved through the tracking of the surgical tools. 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.

Additionally, Neocis Guidance System and the predicate device share several other significant features:

- Both devices have the same Intended Use.
- Both devices provide animated indicators to show the real time location of the surgical tool relative to the patient anatomy, showing the tool in the patient CT in real time.
- Both devices share identical specified environments of use.
- Both devices provide planning software allowing for placement of implant, target surgical site, and guidance to the implant site.

- Both devices provide sub-millimeter guidance accuracy.
- Both devices use CT Scans for registration of the patient tracking attachment, for use in planning the desired implant location, and as a reference to determine the exact positioning of the surgical tools during the surgical procedure.

There are many similarities between the Neocis Guidance System and X-Guide, however there are also some differences (see **Table 2** below for detailed comparison).

The two systems use different tracking methods. X-Guide utilizes LED camera tracking, whereas the Neocis Guidance System uses mechanical tracking. The mechanical tracker eliminates the risk of line-of-sight failures in optical tracking when stereoscopic cameras fail to see the markers on the patient or the surgical tool.

In addition to visual feedback, the Neocis Guidance System also provides physical guidance via the Guidance Arm, which grips the drill and provides constraints to limit the surgeon's motion to match the pre-operative plan. X-Guide only provides visual feedback, which does not physically prevent the surgeon from deviating from the plan.

Technological Characteristics	**NGS (K161399)** **Subject Device**	**X-Guide (K150222)** **Predicate Device**	**IGI-System (K023424)** **Reference Device**	**Justification of Differences**
Use Specifications				
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 surgical procedures and provides navigational guidance of the surgical instruments.	The X-Guide® Surgical Navigation System is a computerized navigational system intended to provide assistance in both the preoperative planning phase and the intra-operative surgical phase of dental implantation procedures. The system provides software to preoperatively plan dental surgical procedures and provides navigational guidance of the surgical instruments. The device is intended for use for partially edentulous and edentulous adult and geriatric patients who need dental implants	The Image-Guided Implantation (IGI) System is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation procedure. The system provides accurate navigational guidance of surgical instruments, with regard to the preoperative planning in dental implantation procedure. The device is intended for use for partially or fully endentulous patients who need dental implants as part of their treatment plan.	No significant difference

Technological Characteristics	NGS (K161399) Subject Device	X-Guide (K150222) Predicate Device	IGI-System (K023424) Reference Device	Justification of Differences
		as part of their treatment plan		
Technology / Performance Characteristics				
Use Environment	Clinical Setting, Doctors Office	Clinical Setting, Doctor's Office	Clinical Setting, Doctor's Office	No difference
Operating Temperature	10 - 35 deg C	10 - 35 deg C	Not Specified	Both systems are intended for use in similar clinical environments.
Operating Relative Humidity	5-95%	30% - 90% non-condensing	Not Specified	Both systems are intended for use in similar clinical environments.
Altitude	500 hPa-1060hPa	500 hPa-1060hPa	500 hPa-1060hPa	No difference
Transport Temperature	0°C to 46°C	-20 - +60 deg C	0 - 40 deg C	No significant difference
Transport Humidity	5-95%	10% - 95% non-condensing	10% - 80% non-condensing	No significant difference
Optical Radiation	N/A	LED, Risk Group 1 (minimal risk) per IEC 62471-1	Laser, Class II (<1mW) per IEC 60825-1, 620-690 nm	NGS has no risk related to optical radiation
Tracking Technology	Mechanical Tracking	Stereo Cameras / LEDs / Pattern	Stereo Cameras / Infrared LEDs	Mechanical tracking provides an alternative tracking method that avoids line-of-sight challenges caused by optical tracking.
Calibration Frequency	Prior to each surgery	Prior to each surgery	Factory Calibrated and authorized service personnel	No difference
Overall System Accuracy (RMS)	<1mm	<1mm	<1mm	No difference
Alarms	Audible, Visual	Audible, Visual	Audible, Visual	No difference
Monitor	LCD-TFT	LCD-TFT	LCD-TFT	No difference

Technological Characteristics	NGS (K161399) Subject Device	X-Guide (K150222) Predicate Device	IGI-System (K023424) Reference Device	Justification of Differences
Communications Interface	Ethernet	Ethernet	Ethernet	No difference
Software	Navigational Guidance and Implant Planning	Navigational Guidance and Implant Planning	Navigational Guidance and Implant Planning	No difference
Dimensions	Height: 73 in (1854.2 mm) Width: 64 in (1625.6 mm) Depth: 34 in (863 mm)	Height: 64.653 in (1642.19 mm) Width: 21.011 in (533.67mm)	Unavailable	Both systems are intended for use in similar clinical environments and are classified as mobile per IEC / EN 60601-1definition.
Mounting Configuration	Mobile Cart	Mobile Cart	Mobile Cart	No difference
Weight	427lbs. (194 kg)	130lbs. (58.97 kg)	Unavailable	Both systems are classified as Mobile, per IEC / EN 60601-1definition. Differences in weight that may exist do not affect either device's efficacy or intended use.
Safety Features				
Electrical Safety	Compliance with the following: IEC 60601-1:2005 + Corr. 1 (2006) + Corr. 2 (2007) 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	IEC 60601-1:2005 3rd Edition AAMI ES60601-1:2005 +A1:2009 +A2:2010 EN 60601-1:2006 ISO15223-1:2012 BS EN ISO 14971:2012	Compliance with the following: EN60601-1:1990 +A1:1992 +A2: 1995; +A13 IEC 601-1:1998 +A1:1991 +A2:1995 +Corrigendum EN60601-1-1:1993 +A1:1995 IEC60601-1-4:1996	Both systems have been tested to equivalent standards.

Technological Characteristics	NGS (K161399) Subject Device	X-Guide (K150222) Predicate Device	IGI-System (K023424) Reference Device	Justification of Differences
	Essential Performance. ISO15223-1:2012 BS EN ISO 14971:2012		EN980:1996 +A1:1999 EN1441:1997	
Electromagnetic Compatibility	Compliance with IEC 60601-1-2:2007	IEC 60601-1-2:2007 3rd Edition	EN 60601-1-2:1993 IEC 601-2:1993	No difference
Biocompatibility	Yes (ISO 10993-1, -5, -10, -11, - 12)	Yes (ISO 10993-1, -5, -10, -11, - 12)	not specified	No difference
Sterilization	Steam	Steam	Steam	No difference
Disinfectant (High-Level)	N/A	3% Glutaraldehyde solution	3% Glutaraldehyde solution	NGS does not use any high-level disinfection.
Ingress Protection	IPX0	IPX2	Not Specified	Both systems are intended for use in similar clinical environments. NGS has drapes for additional ingress protection.
Energy				
Mains Voltage, Frequency	120 VAC; 50 / 60 Hz	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	100 – 127VAC / 200 – 240VAC ; 50 / 60 Hz	No significant difference
Input Power (VA）	600 VA	1500VA	260VA	No significant difference
Fusing Type / Rating	5.0 A for 240 V	Circuit Breaker: 100-127VAC, 10A	Fuse: Qty 2 @ 6A/100-120VAC	Both components perform the same function. The NGS uses a 5.0 A fuse to accommodate a load specific to device components

Technological Characteristics	NGS (K161399) Subject Device	X-Guide (K150222) Predicate Device	IGI-System (K023424) Reference Device	Justification of Differences
Degree of Protection Against Electrical Shock	Applied Part Type BF	Applied Part Type B	Applied Part Type BF	The applied part (Patient Splint) is floating since there is an insulator on the end of the Patient Tracker. However, since the applied part is mechanically linked to the system, the NGS is tested to a higher risk category (Type BF) for protection against electrical shock.
Type of Protection Against Electrical Shock	Class I	Class I	Class I	No difference
Mode of Operation	Continuous	Continuous	Continuous	No difference
Components				
Bone Screw	N/A	Bone Screw	Bone Screw	No bone screw required for NGS
CT Registration	NGS Fiducial Array	X-Clip	Custom Registration Device (CRD) And 3 Point Touch Registration Fixture	Intended use for these items is the same.
Patient Tracking Device	Patient Tracker	X-Corner Patient Tracker	Patient Tracker	Intended use for these items is the same.
Surgical Tool Tracking Device	NGS Guidance Arm	X-Corner Handpiece Tracker	Handpiece Tracker	The physical guidance provided by the NGS Guidance Arm is an additional safety feature to prevent deviations from the plan
Screwdriver	Yes	Yes	Yes	Intended use for these items is the same.

Technological Characteristics	NGS (K161399) Subject Device	X-Guide (K150222) Predicate Device	IGI-System (K023424) Reference Device	Justification of Differences
Patient Tracking Attachment System	Splint	E-Clip	Splint	Intended use for these items is the same.
Drill Bit Length Determination	Depth Gauge and Operator Entry	Go Button	Operator Entry required	Intended use for these items is the same.
Patient Tracker Attachment Arms	Patient Tracker	Posterior Tracker Arm Anterior Tracker Arm	6 Poles – 3 Upper, 3 Lower	Intended use for these items is the same.

Table 2: Summary of Technological Characteristics Comparison

Performance Testing:

Non-clinical Testing:

Biocompatibility Testing

The biocompatibility evaluation for NGS 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 (ISO 10993-5), sensitization and irritation (ISO 10993-10).

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

Cleaning and Sterilization Validation

A representative sample of the re-usable NGS components were tested to validate that the components can withstand the steam sterilization process and that acceptable sterility is achieved using the recommended sterilization protocols. The sterilization validation testing was conducted according to ISO 17665-1:2006 and it validated that the reusable NGS 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 NGS in accordance with various recognized industry standards, by a recognized third party organization. IEC 60601-1:2005 + Corr. 1 (2006) + Corr. 2 (2007) 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 was used for product safety and IEC 60601-1-2:2007 was used for EMC.

Software and System Verification and Validation

Software and system verification and validation testing were conducted, and documentation was provided 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.

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 (May 11, 2005) and FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002).

Risk analysis was conducted 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 (Use FMEA)
- the risks associated with and specific to the design aspects of the device (Design FMEA)
- the risks associated with the electrical safety of the device design as it applies to IEC 60601-1 (60601 FMEA)
- the risks associated with software functionality and software interaction with the user (Software FMEA)

The combined software and system testing and analysis of results (details in **Table 3** below) provide assurance that the device performs as intended.

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

Verification / Validation Type	Description
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).
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)
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.
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.
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.

Verification / Validation Type	Description
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

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

Non-clinical Comparisons to Predicate Device:
Hardware and software verification and validation testing has been performed at the component and system level to confirm the performance of the NGS and assess substantial equivalence claims to the predicate device. Verification tests included:

- Accuracy testing for the Patient Tracker, Guidance Arm, and full system
- Communication rate verification
- Calibration testing
- Emergency use

Internal validation testing was conducted in a simulated clinical environment and included full use of the system through the complete workflow. Testing demonstrated that the device is substantially equivalent to the predicate device.

Clinical Testing:

Clinical testing has been conducted to assess the accuracy, usability, and performance of the NGS, with a primary focus on human factors issues. The study included objective (performance) criteria and subjective (qualitative) criteria evaluated by three surgeons at three different surgical sites over a total of 17 implants placed in 15 patients. The patient population included male and female patients with upper and lower jaw implant requirements.

The primary endpoint was:

- Feasibility of NGS use with regard to human factors issues

It was evaluated using the following criteria:

- Subjective evaluation in a survey using the Likert scale
- Duration for set-up
- Duration for osteotomy preparation
- Splint stability evaluation during surgery

- System deactivation due to patient motion

The secondary endpoint was:

- Feasibility and accuracy of osteotomy preparation using the NGS

It was evaluated using the following criteria:

- Quality of the osteotomy
- Accuracy of the osteotomy relative to the pre-operative plan as measured in pre- and post-operative CT scans

Clinical test results show that use of the NGS is feasible and accurate. The results demonstrated that the NGS enables surgeons to achieve implant accuracy with RMS error < 1mm.

No adverse events or complications have been reported. In comparison to the predicate device, no new issues or risks have been identified.

Conclusion:
The non-clinical and clinical testing demonstrate that the NGS is substantially equivalent to its predicate device when used as intended.