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

February 22, 2018

Re: K173402
Trade/Device Name: Neocis Guidance System (NGS) with Chairside Splint
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: January 22, 2018
Received: January 25, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -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)*
K173402

Device Name
Neocis Guidance System (NGS) with Chairside Splint

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

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Date Prepared: January 22, 2018

Trade Name: Neocis Guidance System (NGS) with Chairside Splint

Common Name: Dental Stereotaxic Instrument

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

Classification: Class II

Product Code: PLV

Predicate Device: Neocis Guidance System (K161399)

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. 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.

The subject device is the same as the NGS cleared under K161399 (the predicate device), except for a change to the splint. The Patient Splint of the predicate device has been modified to allow for a chairside workflow. This modified splint is referred to as the Chairside Splint.

The splint is a key component for patient tracking for the NGS. The patient tracking portion of the NGS is comprised of the Chairside Splint and the Patient Tracker. The Chairside Splint is attached to the contralateral side of the patient's mouth. The Chairside Splint is affixed to the patient's teeth using Lang Jet Tooth Shade Dental Acrylic (K083195). The Chairside Splint is placed on the patient prior to the CT scan. A fiducial array with fiducial markers is placed on the Chairside 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 Chairside 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.

Comparison of Technological Characteristics:

This submission involves only a modification to the Patient Splint for the NGS. The new version will be referred to as the Chairside Splint, to be differentiated from the previous Patient Splint. Otherwise, all performance characteristics of the NGS are the same. The Chairside Splint involves a modification that allows for a chairside creation of the Patient Splint rather than requiring a patient impression and model and fabrication through a dental lab. The differences introduced by this modification are detailed in **Table 1**.

Technological Characteristics	**NGS with Chairside Splint** **Subject Device**	**NGS with Patient Splint** **Predicate Device (K161399)**	**Comments**
Indications for Use			
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 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.	No difference
Materials			
Materials	Ixef®-HC-1022	Ixef®-HC-1022	No difference
Technology / Performance Characteristics			
Supply Voltage	120 V	120 V	No difference
Phases	1	1	No difference
Type of Current	AC	AC	No difference
Rated Frequency (Hz)	60 Hz	60 Hz	No difference
Rated Power Input (VA)	600 VA	600 VA	No difference
Types and Ratings of external accessible fuses	5.0 A for 240 V	5.0 A for 240 V	No difference
Type of Protection against Electric Shock	Class I Equipment	Class I Equipment	No difference
Degree of Protection against Electric Shock	Type BF	Type BF	No difference

Technological Characteristics	NGS with Chairside Splint Subject Device	NGS with Patient Splint Predicate Device (K161399)	Comments
Equipment Suitable for use in the presence of Flammable Mixtures?	No	No	No difference
Mode of Operation	Continuous Operation	Continuous Operation	No difference
System Lateral Accuracy	RMS < 1 mm	RMS < 1 mm	No difference
System Depth Accuracy	RMS < 1 mm	RMS < 1 mm	No difference
System Angular Accuracy	RMS < 6.0°	RMS < 6.0°	No difference
CT Scan Quality Requirements	0.3 mm Voxel, 0.3 mm Slice Thickness, Matrix 512x512, Full 13cm 21 sec, Multi 2 DICOM format.	0.3 mm Voxel, 0.3 mm Slice Thickness, Matrix 512x512, Full 13cm 21 sec, Multi 2 DICOM format.	No difference
F/T Sensor Force Measurement Range	+/- 30 N	+/- 30 N	No difference
F/T Sensor Torque Measurement Ra nge	+/- 2 Nm	+/- 2 Nm	No difference
F/T Sensor Single Axis Force Overload Limit	200 N	200 N	No difference
F/T Sensor Single Axis Torque Overload Limit	20 Nm	20 Nm	No difference
Upper limit specification for Guidance Arm Translation Speed	1.25 m/s	1.25 m/s	No difference
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.	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.	No difference
Splint Attachment	Chairside Splint can be attached chairside with use of acrylic or developed with acrylic on a patient model in a dental lab.	Patient Splint is developed with acrylic on a patient model in a dental lab.	Difference in splint attachment has been verified and validated through nonclinical and clinical testing.
Splint Removal	Chairside Splint may be removed either by cutting bridges along a seam of the splint or manually pulling off.	Patient Splint is removed by manually pulling off.	Difference in splint removal has been verified and validated through nonclinical and clinical testing.
Fiducial Array Attachment to	The Fiducial Array attaches to the splint during the CT scan to	The Fiducial Array attaches to the splint during the CT scan to	No difference

Technological Characteristics	NGS with Chairside Splint Subject Device	NGS with Patient Splint Predicate Device (K161399)	Comments
Splint	provide a reference in the image.	provide a reference in the image.	
Kinematic Mount Attachment to Splint	The Kinematic Mount attaches to the splint to provide a mounting point for the Fiducial Array and Patient Tracker.	The Kinematic Mount attaches to the splint to provide a mounting point for the Fiducial Array and Patient Tracker.	No difference
Splint Shape and Kinematic Mount Location	The shape of the splint and the location of the Kinematic Mount attachment point are designed to allow for proper ergonomic approach of the Patient Tracker and Guidance Arm.	The shape of the splint and the location of the Kinematic Mount attachment point are designed to allow for proper ergonomic approach of the Patient Tracker and Guidance Arm.	No difference
Safety Features			
Biocompatibility	Yes (ISO 10993-1, -5, -10, -11, -12)	Yes (ISO 10993-1, -5, -10, -11, -12)	No difference
Sterilization	Steam	Steam	No difference. Both splint versions are disposable and one-time use.
Components			
Patient Tracking Device	Patient Tracker	Patient Tracker	No difference
Patient Tracking Attachment System	Chairside Splint	Patient Splint	Intended use for these items is the same.

Table 1: Summary of Technological Characteristics Comparison

Performance Testing:

Non-clinical Testing

Chairside Splint verification and validation testing is described below in **Table 2**.

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.

Table 2: Summary of component and system verification and validation.

The subject of this 510(k) was only a modification to the patient splint. As such, non-clinical testing performed in support of clearance of the predicate NGS itself did not need to be repeated. Below is a list of the non-clinical testing performed on the predicate NGS that were relied upon for clearance of the modified splint.

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.
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.

Verification / Validation Type	Description
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.
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

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

Nonclinical 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 to the predicate device. Verification tests included:

- Patient Splint attachment, stability, and removal testing
- Total system use testing

Nonclinical 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 application and removal of the Chairside Splint, with a primary focus on human factors issues. The study included objective criteria and subjective criteria evaluated by 15 dentists at two different sites over a total of 75 subjects. The investigator population included a variety of experience levels and the subject population included both upper and lower jaw testing.

The primary study endpoint was:

- Evaluation of human factors regarding Chairside Splint application and removal

It was evaluated using the following criteria and data:

- Duration of Chairside Splint application and removal
- Photos and intra-oral scans of the site before and after Chairside Splint placement
- Occurrence of adverse events related to acrylic fixation
- Occurrence of adverse events during removal due to drilling the Chairside Splint
- Occurrence of adverse events due to debris or other swallowing or aspiration potential hazards
- Subjective evaluation by Investigators

Study results support the substantial equivalence of the NGS Chairside Splint to the cleared Patient Splint.

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

Conclusion:

The nonclinical and clinical testing demonstrated that the modified splint is substantially equivalent to the predicate device splint when used as intended.