September 11, 2019

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

Re: K191605
Trade/Device Name: Neocis Guidance System (NGS)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: June 12, 2019
Received: June 17, 2019

Dear Thomas 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 Nandkumar, PhD
Acting Assistant 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191605

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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Date Prepared: September 11, 2019

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: Neocis Guidance System (NGS) with Chairside Splint (K182776)

Reference Devices: Aseptico VCT Versatile Control Technology Model AEU-925 (K030163), Montblanc Implantology Contra-angle Control (K070084), Neocis Guidance System (K161399), and Neocis Guidance System with Chairside Splint (K173402)

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 K182776 (the predicate device), except for a change to the dental drill supplier and dental drill collar design. The dental handpiece and motor have received previous 510(k) clearance under K070084

and K030163.

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 dental materials specified in the labeling. 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 a modification to the dental drill supplier and to the dental drill collar design. Otherwise, all performance characteristics of the NGS are the same. The differences introduced by this modification are detailed in the table 1 below.

Table 1: Summary of Technological Characteristics Comparison

Technological Characteristics	**NGS** **Subject Device**	**NGS with Chairside Splint** **Predicate Device (K182776)**	**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
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

Technological Characteristics	NGS Subject Device	NGS with Chairside Splint Predicate Device (K182776)	Comments
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
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

Technological Characteristics	NGS Subject Device	NGS with Chairside Splint Predicate Device (K182776)	Comments
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.	Chairside Splint can be attached chairside with use of acrylic or developed with acrylic on a patient model in a dental lab.	No difference
Dental materials (acrylics or resins)	• Alike (K942670-GC Pattern Resin) • Cool Temp Natural (K041098) • 3M ESPE ProTemp Plus (K033022-Protemp 3 Garant) • Visalys Core (UV light curable) (K143104) • EZ Pickup (UV light curable) (K984341-SternVantage Varnish LC Model 221001) • Ufi Gel hard C (K030916) • Triad C&B Material (UV light curable) (K850911)	• Alike (K942670-GC Pattern Resin) • Cool Temp Natural (K041098) • 3M ESPE ProTemp Plus (K033022-Protemp 3 Garant) • Visalys Core (UV light curable) (K143104) • EZ Pickup (UV light curable) (K984341-SternVantage Varnish LC Model 221001) • Ufi Gel hard C (K030916) • Triad C&B Material (UV light curable) (K850911)	No difference
Splint Removal	Chairside Splint may be removed either by cutting bridges along a seam of the splint or manually pulling off.	Chairside Splint may be removed either by cutting bridges along a seam of the splint or manually pulling off.	No difference
Fiducial Array Attachment to Splint	The Fiducial Array attaches to the splint during the CT scan to provide a reference in the image.	The Fiducial Array attaches to the splint during the CT scan to provide a reference in the image.	No difference
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

Technological Characteristics	NGS Subject Device	NGS with Chairside Splint Predicate Device (K182776)	Comments
Sterilization	Steam	Steam	No difference.
Components			
Patient Tracking Device	Patient Tracker	Patient Tracker	No difference
Patient Tracking Attachment System	Chairside Splint	Chairside Splint	No difference
Dental Drill Motor and Hand Piece	• Aseptico Drill Motor (Model No. AEU-7000LNE-70V) (K030163) • Anthogyr Mont Blanc handpiece (Aseptico Model No. AHP-85MBFO-CX) (K070084)	W&H Implant Med Electric Drill Motor (Implant Med SI 95 Series), and an Anthogyr Impulsion handpiece (Model No. 14400BP)	Brand change, functionally equivalent
Drill Motor Collar	• Geometry to fit Aseptico • Increased size • Compression collet to improve rigidity	• Geometry to fit W&H • Smaller size • Tension clamp for rigidity	Increased robustness of the design to improve rigidity and to accommodate different drill brand

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
Boundary Condition	Testing of all potential boundary parameters in the Application Software
Registration	Testing of registration process

Verification / Validation Type	Description
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)
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.

Verification / Validation Type	Description
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

Performance Testing Submitted with this Submission

- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Applications of risk management to medical devices
- ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- 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
- Neocis-Total system accuracy verification
- Neocis-End user validation
    - Simulated procedure on typodont

Conclusion:

The indications for use are unchanged. The technological changes do not raise different questions of safety and effectiveness. The new parts perform in a substantially equivalent manner to the predicates.