October 19, 2020

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

Re: K202100
Trade/Device Name: Neocis Guidance System (NGS) with Clamped Chairside Patient Splint (C-CPS)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: July 24, 2020
Received: July 29, 2020

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 “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)*
K202100

Device Name
Neocis Guidance System (NGS) with Clamped Chairside Patient Splint (C-CPS)

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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510(k) Summary – K202100

I. Submitter

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

Contact Person: Thomas Claiborne, Ph.D., Regulatory Affairs Manager
Date Prepared: October 19, 2020

II. Device

Trade Name: Neocis Guidance System (NGS) with Clamped Chairside Patient Splint (C-CPS)
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

- Neocis Guidance System (NGS) with Chairside Splint (K173402)

IV. 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.

V. Device Description:

In terms of FDA regulations, the Neocis Guidance System (NGS) is a dental stereotaxic instrument (Product Code PLV) and a powered surgical device for bone cutting (21 CFR 872.4120).

In terms of previously FDA-cleared indications for use, the Neocis Guidance System (NGS) (K161399) 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 system allows the user to plan the surgery virtually in our Neocis Planning Software

Application installed on the NGS planning station or on a 3rd party PC (K191363). The operative plan is based on a cone beam computed tomography (CBCT) scan of the patient, which is used to create a 3-D model of the patient anatomy in our planning software. The plan is used by a guidance system to provide physical, visual, and audible feedback to the surgeon during the implant site preparation. The NGS robotic arm holds and guides a standard FDA-cleared powered bone cutting instrument (K191605).

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 NGS 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 implant process occurs in two phases: (1) The dental surgeon plans the surgical procedure with the planning software, on the day of surgery or sometime prior if a pre-operative CT scan was taken at an earlier visit. A virtual dental implant, selected from the dental implant library or using a generic model, both contained within our planning software, is placed at the desired location in the patient model. The software highlights critical anatomical structures to avoid, such as the inferior alveolar nerve. (2) When the dental implant plan is optimized, the NGS provides precise and accurate guidance of the dental surgical instruments according to the pre-operative plan. The NGS robotic arm, which holds the surgical instrument, 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 surgeon may modify the plan intraoperatively, if needed, has direct visualization of the patient anatomy, and is always in control of the surgical instrument.

Key safety features include:

- Emergency stop
- Safety pause
- Audio and visual queues
- Drill torque limits
- Surgeon control

The subject device in this submission is the new Clamped Chairside Patient Splint (C-CPS). The C-CPS offers our users an alternative to acrylic-type dental material affixation. The subject device replaces the acrylic-type dental material locking mechanism of affixation with a clamp-like mechanism of affixation using softer dental impression (registration) material, alignment slots, and an approximation screw. The clamping screw is not a bone screw, and it does not

interact directly with the patient. The screw is positioned above the teeth inside the splint. The subject device is essentially a CPS (K173402) that has been bisected lengthwise with screw holes and alignment slots in each half to approximate the two halves around the patient's stable teeth. The dental impression material is placed inside the splint to form a tight conformational gripping surface between the splint and the teeth. The dental impression material conforms the shape of the patient's teeth to form a large gripping surface area. The C-CPS initial placement is like a dental impression tray. A torque-brake screwdriver with hex bit is used to tighten and loosen the screw. The proper C-CPS model (left/right or anterior/posterior) should be selected based upon the accommodation of the patient's anatomy and the intended surgical location.

VI. Comparison of Technological Characteristics:

The indications for use (IFU) of the subject device have remained unchanged from the predicate device Acrylates allergy contraindication is not applicable to the C-CPS. There are no changes to the non-splint NGS hardware or software in this submission.

Table 1. Comparison of Technologies Characteristics

Technological Characteristics	**NGS with C-CPS** ***Subject Device***	**NGS with CPS K173402** ***Predicate Device***	**SE Analysis**
Patient Contacting Materials	Ixef®-HC-1022	Same as the subject device	Identical
NGS Power Supply	120VAC/60 Hz	Same as the subject device	Identical
Type of Protection against Electric Shock	Class I Equipment	Same as the subject device	Identical
Equipment Suitable for use in the presence of Flammable Mixtures?	No	Same as the subject device	Identical
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)	Same as the subject device	Identical

Technological Characteristics	NGS with C-CPS *Subject Device*	NGS with CPS K173402 *Predicate Device*	SE Analysis
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	Same as the subject device	Identical
Ingress Protection	IPX0	Same as the subject device	Identical
Mode of Operation	Continuous Operation	Same as the subject device	Identical
System Lateral Accuracy	RMS < 1 mm	Same as the subject device	Identical
System Depth Accuracy	RMS < 1 mm	Same as the subject device	Identical
System Angular Accuracy	RMS < 6.0°	Same as the subject device	Identical
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	Identical
F/T Sensor Force Measurement Range	+/- 30 N	Same as the subject device	Identical
F/T Sensor Torque Measurement Ra nge	+/- 2 Nm	Same as the subject device	Identical
F/T Sensor Single Axis Force Overload Limit	200 N	Same as the subject device	Identical
F/T Sensor Single Axis Torque Overload Limit	20 Nm	Same as the subject device	Identical
Upper limit specification for Guidance Arm Translation Speed	1.25 m/s	Same as the subject device	Identical

Technological Characteristics	NGS with C-CPS *Subject Device*	NGS with CPS K173402 *Predicate Device*	SE Analysis
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.	Same as the subject device	Identical
Splint Purpose	Physical linkage to patient via Patient Tracker and Kinematic Mount connected to: • C-CPS, or • CPS (K173402)	Same as the subject device	Addition of C-CPS to NGS workflow.
Splint Models	-Posterior (left & right) -Anterior (left & right); Each with one aluminum screw	-Posterior (left & right) -Anterior (left & right)	Addition of screw
Splint Volume	Approximately 16k mm^3	Approximately 13k mm^3	Subject device approximately 20% larger than predicate
Splint Surface Area	Anterior Model: -Mucosa: 206 mm^2 -Teeth: 1062 mm^2 Posterior Model: -Mucosa: 155 mm^2 -Teeth 898 mm^2	Anterior Model: -Mucosa: 200 mm^2 -Teeth: 725 mm^2 Posterior Model: -Mucosa: 65 mm^2 -Teeth 583 mm^2	C-CPS is % Larger than CPS: Anterior Model: -Mucosa: 3% -Teeth: 46% Posterior Model: -Mucosa: 140% -Teeth: 54%
Patient Contacting Materials	-IXEF -#8-32 UNC 6061 aluminum screw -316 Stainless steel hex bit	-IXEF	Addition of screw and screwdriver bit materials
Splint Application Tools	-Torque-brake screwdriver set to 1.8Nm with 9/64-inch hex bit; -Dental material applicator	Dental material applicator	Added screwdriver
Dental Materials Used with the Splints	Dental impression material DMG O-Bite (Luxabite K013236)	Lang Jet Tooth Shade (K083195) (Additional materials cleared in K182776)	Use of softer impression materials instead of hard acrylic-like materials, both FDA-cleared for dental use

Technological Characteristics	NGS with C-CPS *Subject Device*	NGS with CPS K173402 *Predicate Device*	SE Analysis
Splint Affixation	Clamping and gripping teeth with compressive force and dental impression material grip (friction force)	Hardening and locking of dental materials to teeth (with mild compression due to material shrinkage)	Reliance on increased compression force for fixation
Splint removal	Backing out clamping screw and manually separating the two halves	CPS can be removed manually or by powered cutting tool	Splint cutting not needed
Dental Material Removal	Standard dental techniques	Same as subject device	Identical
Fiducials	Fiducial Array (FA) attached to splint	Same as the Subject Device	NGS Fiducial is not patient contacting
Kinematic mount	Integrated into the splint	KM as separate part	Similar implementation
Biocompatibility	Yes (ISO 10993-1, -5, -10, -12)	Same as the Subject Device	Identical
Sterilization	Provided nonsterile User sterilized by Steam (ISO 17665-1)	Same as the Subject Device	Identical
Use	Splint single use only Tools reusable	Splint single use only	Addition of tools for subject device
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)	Same as the Subject Device	Aseptico cleared for use with NGS under K191605, NGS guidance arm cleared under K161399
Planning Software	• Neocis Planning Software Application v1.2 (K161399), or • Neocis Planning Software Application for 3rd Party PCs v1.8.1 (K191363)	Same as the Subject Device	Identical

Technological Characteristics	NGS with C-CPS *Subject Device*	NGS with CPS K173402 *Predicate Device*	SE Analysis
Software Level of Concern	Moderate	Same as the Subject Device	Identical

Comparison of the Indications for Use and Contraindications

The indications for use (IFU) of the subject device are identical to the predicate device. Acrylates allergy contraindication was removed since it is no longer applicable.

Table 2. Comparison of the Indications for Use and Contraindications

Technological Characteristics	NGS with C-CPS *Subject Device*	CPS K173402 *Predicate Device*	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 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	Identical

Technological Characteristics	**NGS with C-CPS** ***Subject Device***	**CPS K173402** ***Predicate Device***	**SE Analysis**
Contraindications	The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a Neocis Chairside Patient Splint (CPS) rigidly throughout a surgical procedure. The Neocis Chairside Patient Splint (CPS) should not be affixed to patients that exhibit: • Periodontal disease to include loose teeth and inflamed tissue • Fixed orthodontic appliances, bridges, or dental implants • Patients with a history of jaw or TMJ pain	The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a Neocis Chairside Patient Splint (CPS) rigidly throughout a surgical procedure. The Neocis Chairside Patient Splint (CPS) should not be affixed to patients that exhibit: • Periodontal disease to include loose teeth and inflamed tissue • Fixed orthodontic appliances, bridges, or dental implants • Patients with a history of jaw or TMJ pain • Patients with allergies to methyl methacrylates	Acrylates allergy contraindication not needed

VII. Performance Testing

Use of FDA-Recognized Consensus Standards

A risk analysis, sterilization validation, and biocompatibility testing were conducted on the final finished device per the following standards:

- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Applications of risk management to medical devices
- 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
- ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ANSI AAMI ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ANSI AAMI ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Verification

- Clamped Chairside Patient Splint (C-CPS) Splint Deflection Test with Optical Tracking
- Clamped Chairside Patient Splint (C-CPS) Pressure Assessment (Teeth)
- Clamped Chairside Patient Splint (C-CPS) Kinematic Mount Repeatability
- Clamped Chairside Patient Splint (C-CPS) Pressure Assessment (Soft Tissue)
- Clamped Chairside Patient Splint (C-CPS) Removal Force Test
- Clamped Chairside Patient Splint (C-CPS) DOE for Parameter Evaluation
- Clamped Chairside Patient Splint (C-CPS) Screw Failure Test
- Clamped Chairside Patient Splint (C-CPS) Lingual-Buccal Assembly Failure Torque
- Dimension Analysis (Clamped Chairside Patient Splint (C-CPS) vs. Chairside Patient Splint (CPS))
- Total System Accuracy

Validation

- C-CPS Technique Validation: Simulated Clinical Testing
    - To validate the user requirements of the C-CPS, as performed by a surgeon (end-user). This validation activity is a nonclinical surrogate that simulates the process of applying, qualitatively evaluating rigidity, and removing a C-CPS directly to a patient.

Animal or clinical testing was not conducted for the subject device.

Conclusion:

The C-CPS is substantially equivalent to the predicate. There are no changes to the intended use or to the fundamental technology.