May 8, 2020

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

Re: K200348
Trade/Device Name: Neocis Guidance System (NGS) with Fiducial Array Splint (FAS)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: February 11, 2020
Received: February 12, 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)*
K200348

Device Name
Neocis Guidance System (NGS) with Fiducial Array Splint (FAS)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Contact Person:
Thomas Claiborne, Ph.D.
2800 Biscayne Blvd.
Suite 600
Miami, FL 33137
Tel: 1-855-9NEOCIS

Date Prepared: May 7, 2020

Trade Name: Neocis Guidance System (NGS) with Fiducial Array Splint (FAS)

Common Name: Dental Stereotaxic Instrument

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

Classification: Class II

Product Code: PLV

Primary Predicate Device: Neocis Guidance System (NGS) with Chairside Splint (K173402)

Reference Devices: Neocis Guidance System (K191605) & Neocis Guidance System (K182776)

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) (K161399) is a dental stereotaxic instrument (Product Code PLV) and a powered surgical device for bone cutting (21 CFR 872.4120). The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments, with

regard to pre-operative planning in dental implantation procedures. The system allows the user to plan the surgery virtually in software using a cone beam computed tomography (CBCT) scan of the patient, and the plan is used by a guidance system to provide physical, visual, and audible feedback to the surgeon during the implant site preparation. The holds and guides a standard FDA-cleared powered bone cutting instrument.

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

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

The subject device is a design variation of the predicate CPS (K173402). The portion of the splint that attaches to the patient now contains the fiducial markers. We are calling the subject device, the Fiducial Array Splint (FAS). This provides an alternative workflow in which the FA is not needed. These are the only changes in this submission. The NGS is otherwise the same as the cleared device (K161399). The indications for use and contraindications for the subject and predicate devices are the same.

Since the fiducial markers are on the portion of the splint that is affixed using dental material, we do have to limit the use of cleared dental materials (K182776) to those that are not radio-opaque:

- 3M ESPE ProTemp Plus
- Alike
- Traid C&B Material (UV light curable)

The other dental materials cleared for use with the CPS cannot be used with the FAS.

Since the FAS does need the FA, we can use the FAS in CBCT scanners with smaller scan volumes and standard chin rests.

Comparison of Technological Characteristics:

This submission involves only a modification to the CPS, referred to as the FAS, to be differentiated from the other Neocis splints. Otherwise, all performance characteristics of the NGS are the same. The differences introduced by this modification are detailed in Table 1.

Table 1: SE Summary

Technological Characteristics	Subject Device	Predicate K173402	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 accurate navigational guidance of surgical instruments, with regard to pre-operative planning in dental implantation procedures.	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 accurate navigational guidance of surgical instruments, regarding pre-operative planning in dental implantation procedures.	Identical
Technology / Performance Characteristics			
Power supply	120VAC/60Hz	120VAC/60Hz	Identical
Splint Attachment Using Dental Materials	• 3M ESPE ProTemp Plus (K033022) • Alike (K942670) • Traid C&B Material (UV light curable) (K850911) **Radio-opaque dental materials not recommended*	Lang Jet Tooth Shade (K083195)	Additional radio-transparent dental materials from reference device K182776
Splint Removal	FAS may be removed either by cutting bridges along a seam of the splint or manually pulling off.	CPS may be removed either by cutting bridges along a seam of the splint or manually pulling off.	Identical
Fiducial Array (FA)	Not required	The Fiducial Array attaches to the splint during the CT scan to provide a reference in the image.	Fiducial beads relocated to the FAS
Kinematic Mount (KM)	KM integrated into the FAS	KM screwed to CPS and FA	Simpler interface, less parts

Technological Characteristics	Subject Device	Predicate K173402	SE Analysis
Splint Materials	• IXEF-HC-1022 • Aluminum 2017 • Epoxy (EPO-TEK 353ND)	IXEF-HC-1022	Addition of fiducial marker and adhesive materials
Safety Features			
Biocompatibility	Tissue, bone, dentin contact < 24 hrs ISO 10993-1, -5, -10, -12	Tissue, bone, dentin contact < 24 hrs ISO 10993-1, -5, -10, -12	Identical
Sterilization	Steam, by end user, reusable ISO 17665-1	Steam, by end user, reusable ISO 17665-1	Identical
Components			
Patient Tracking Device	Patient Tracker (PT) with End Effector (EE)	Patient Tracker (PT) with End Effector (EE)	Identical
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) • Anthogyr Impulsion handpiece (Model No. 14400BP)	Brand change, functionally equivalent (Reference Device K191605)
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 (Reference Device K191605)
Other NGS Technology	No changes	No changes	Identical
NGS Software (Planning and Control)	No changes	No changes	Identical

Performance Testing Submitted with this Submission:

Use of FDA-Recognized Consensus 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

Additional Neocis Performance Testing

1. Bite force testing on fiducial markers
2. Cut removal
3. Loaded splint deflection testing using 2x PT weight
4. Simulated clinical use: end user validation on a typodont
5. Fiducial marker registration
6. Fiducial marker single use autoclave test
7. Total system accuracy testing

Conclusion:

There are no changes to the intended use of the subject device. Our performance testing demonstrates substantially equivalent performance of the subject device as compared to the predicate device. Therefore, the FAS is substantially equivalent to the predicate.