December 15, 2020

Neocis Inc.
Thomas E. Claiborne, Ph.D.
Regulatory Affairs Manager
2800 Biscayne Blvd Suite 600
Miami, Florida 33317

Re: K203401
Trade/Device Name: Neocis Guidance System (NGS) with Patient Splints (EPS)
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: November 18, 2020
Received: November 19, 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,

Michael Adjodha, M.ChE.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203401

Device Name
Neocis Guidance System (NGS) with Edentulous Patient Splint (EPS)

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. The NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

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

I. Submitter

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

Contact Person: Thomas E. Claiborne, Ph.D., Regulatory Affairs Manager
Date Prepared: November 18, 2020

II. Device

Trade Name:	Neocis Guidance System (NGS) with Edentulous Patient Splint (EPS)
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 Patient Splints (K200805)

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. The NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

V. 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 precise and 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 for partially edentulous patients include the Chairside Patient Splint (CPS) (K173402) or the Clamped Chairside Patient Splint (CCPS) (K202100), the End Effector (EE) and the Patient Tracker (PT). The CPS or CCPS 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 splint 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 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, position, and depth to accommodate the patient movement, which will maintain the accuracy of the osteotomy.

The subject of this submission is a design change to the sleeves in our Edentulous Patient Splint (EPS) (K200805). The EPS enables use of the NGS in fully edentulous patients. It is affixed to the anterior mandible or maxilla using standard bone screws. Like the CPS and CCPS, the EPS serves as rigid connection to the patient for robotic tracking of the patient during the procedure. The EPS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

VI. Comparison of Technological Characteristics

This submission includes a design change to the sleeves in the EPS. There are no changes to the indications for use. There are no changes to the NGS hardware or software in this submission. The differences introduced by this modification are detailed in Table 1.

Table 1: Comparison of technological characteristics to the predicates

Technological Characteristics	Subject Device	Predicate K200805	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 NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.	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 NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.	Identical
NGS Technology (non-splint hardware and software)	No changes	No Changes	Identical
Patient Splint	EPS	EPS	Identical
Splint Sleeves	Neocis design titanium	Third party stainless steel (K190059)	Material & manufacturing change
Patient Contacting Materials	• Ixef®-HC-1022 • Titanium Alloy	• Ixef®-HC-1022 • Stainless Steel • Titanium Alloy	Removed stainless steel
Patient Tracking	Physical linkage to patient via Patient Tracker, Kinematic Mount, and End Effector connected to: • EPS	Physical linkage to patient via Patient Tracker, Kinematic Mount, and End Effector connected to: • EPS	Identical

Technological Characteristics	Subject Device	Predicate K200805	SE Analysis
Affixation of tracking technology to patient	Stryker Mandibular Fracture and Reconstruction Fixation System, Bone Fixation Screws 2.0, 2.3 mm Diam, 10 – 20 mm length (K014263)	Stryker Mandibular Fracture and Reconstruction Fixation System, Bone Fixation Screws 2.0, 2.3 mm Diam, 10 – 20 mm length (K014263)	Identical
Patient attachment removal	EPS is removed by unscrewing the bone screws	EPS is removed by unscrewing the bone screws	Identical
Fiducials	Fiducial Array (FA) attached to splint	Fiducial Array (FA) attached to splint	Identical
Kinematic mount	Integrated into the splint	Integrated into the splint	Identical

VII. Performance Testing

The subject of this 510(k) was a design change to the sleeves in the EPS. There are no other system or labeling changes in this submission.

- EPS Weighted Deflection Test with Optical Tracking in Sawbones®
- Total System Accuracy
- ANSI AAMI ISO 14971:2019 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 device
- 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
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ANSI AAMI ISO 10993-12: 2012 Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials

VIII. Conclusion

The design changes to the EPS sleeves have been verified using well established methods. The new design is functionally the same as the predicate device. The subject device does not raise different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate.