December 4, 2020

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

Re: K202264
Trade/Device Name: Neocis Guidance System (NGS) with Yomi Plan v2.0
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: September 4, 2020
Received: September 10, 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)*
K202264

Device Name
Neocis Guidance System (NGS) with Yomi Plan v2.0

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.

When Yomi Plan software is used for preplanning on third party PCs, it is intended to perform the planning (pre-operative) phase of dental implantation surgery. Yomi Plan provides pre-operative planning for dental implantation procedures. The output of Yomi Plan is to be used with the Neocis Guidance System (NGS).

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

K202264

I. Submitter

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

Contact Person: Thomas Claiborne, Ph.D., Regulatory Affairs Manager
Date Prepared: December 3, 2020

II. Device

Trade Name: Neocis Guidance System (NGS) with Yomi Plan v2.0
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

- Primary Predicate:
  - Neocis Guidance System (NGS) (K161399)
- Reference Devices
  - Neocis Planning Software Application for 3rd Party PCs (K191363)
  - Neocis Guidance System (NGS) with Edentulous Patient Splint (EPS) (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.

When Yomi Plan software is used for preplanning on third party PCs, it is intended to perform the planning (pre-operative) phase of dental implantation surgery. Yomi Plan provides pre-operative planning for dental implantation procedures. The output of Yomi Plan is to be used with the Neocis Guidance System (NGS).

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 (K200805), 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 system allows the user to plan the surgery virtually in Yomi Plan (K191363-cleared for use alone on third party PCs for preplanning). 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 third party 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) or Edentulous Patient Splint (EPS) (K200805), 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. The EPS is placed using bone screws prior to the presurgical CBCT scan (appropriate local anesthesia is required). 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
- Full surgeon control and direct visualization of the surgical field

The Neocis Guidance System (NGS) with Yomi Plan v2.0 is a "catch-up" focused on the planning software and presenting changes made from v1.2 (K161399) to the current release

v2.0 (wireless network capabilities, interface updates, etc.). The Neocis Guidance System (NGS) contains two software packages: (1) planning and (2) control. Each resides on a separate PC on the device: (1) planning station laptop PC and (2) control PC in the cart base. There are no changes to the control software or the NGS hardware in this submission. The use of TeamViewer has been implemented to access NGS systems that connected to external networks to examine system performance for postmarket.

VI. Comparison of Technological Characteristics

This submission is focused on an update to our planning software, Yomi Plan v2.0, and adds wireless network capabilities to the system primarily for CBCT file transfer during the planning phase of the procedure. During the osteotomy (guidance) phase of the procedure, the system disables the wireless network connection. Once the osteotomy portion of the procedure is completed and exited in the software application, the wireless network connection is reenabled.

Table 1: Comparison of technological characteristics to the predicates

Feature	**Subject Device: NGS with Yomi Plan v2.0**	**Predicate 1: NGS K161399**	**Predicate 2: Neocis Planning and Guidance Software for 3rd Party PCs K191363**	**Predicate 3: NGS with Edentulous Patient Splint K200805**	**SE Analysis**
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. When Yomi Plan software is used for preplanning on third party PCs, it is intended to perform the planning (pre-operative) phase of dental implantation surgery. Yomi Plan provides pre-operative planning for dental implantation procedures. The output of Yomi Plan is to be used with the Neocis Guidance System (NGS).	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 Planning Software Application (NPSA) for 3rd Party PCs is intended to perform the planning (pre-operative) phase of dental implantation surgery. The NPSA provides pre-operative planning for dental implantation procedures. The output of the NPSA is to be used with the Neocis Guidance System.	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.	Subject device combines indications from the predicates. Rebrand as “Yomi Plan.”

Feature	Subject Device: NGS with Yomi Plan v2.0	Predicate 1: NGS K161399	Predicate 2: Neocis Planning and Guidance Software for 3rd Party PCs K191363	Predicate 3: NGS with Edentulous Patient Splint K200805	SE Analysis
Yomi Plan Software Version	v2.0	v1.2	v1.8.1	v1.10 (not a subject of the submission)	Updated GIU, network connectivity, remote access added
OS	Windows 10	Windows 7	Windows 7	Windows 10	Remains Windows based
PC Requirements	PC with 64-bit Windows 10 OS or newer with a minimum of 4 GB of RAM and a 2 GHz dual core processor. Local memory (hard drive) should be a minimum of 100 GB with 7200 RPM or SSD. Connectivity requirements include ethernet, Wi-Fi, USB, or CD drive.	PC with 64-bit Windows 7 OS or newer with a minimum of 4 GB of RAM and a 2 GHz dual core processor. Local memory (hard drive) should be a minimum of 100 GB with 7200 RPM or SSD. USB or CD drive.	PC with 64-bit Windows 7 OS or newer with a minimum of 4 GB of RAM and a 2 GHz dual core processor. Local memory (hard drive) should be a minimum of 100 GB with 7200 RPM or SSD. USB or CD drive.	PC with 64-bit Windows 7 OS or newer with a minimum of 4 GB of RAM and a 2 GHz dual core processor. Local memory (hard drive) should be a minimum of 100 GB with 7200 RPM or SSD. USB or CD drive.	Added network connectivity via ethernet or Wi-Fi
Yomi Plan Functions	• Load CT Scanned Image • Optimize Image • Plan Procedure (place implant) • Save Surgical Plan • Connect to Control software • Provide Feedback to Surgeon regarding physical location of Drill and Drill components • Select Surgical Phase • Set areas for mechanical restriction during surgical operation • Visualize CT Scanned Image with 2D Slices • Generate Panoramic reconstruction along arch • Visualize Panoramic reconstruction with cross sections along panoramic arch • Map Splint coordinate	• Load CT Scanned Image • Optimize Image • Plan Procedure (place implant) • Save Surgical Plan • Connect to Control software • Provide Feedback to Surgeon regarding physical location of Drill and Drill components • Select Surgical Phase • Set areas for mechanical restriction during surgical operation • Visualize CT Scanned Image with 2D Slices • Generate Panoramic reconstruction along arch • Visualize Panoramic reconstruction with cross sections along panoramic arch • Map Splint coordinate	• Load CT Scanned Image • Optimize Image • Plan Procedure (place implant) • Save Surgical Plan • Visualize CT Scanned Image with 2D Slices • Generate Panoramic reconstruction along arch • Visualize Panoramic reconstruction with cross sections along panoramic arch • Define anatomical planes • Clip CT Scanned Images • Define Arch for generating panoramic reconstruction • Provide the user with a means to define a nerve	• Load CT Scanned Image • Optimize Image • Plan Procedure (place implant) • Save Surgical Plan • Connect to Control software • Provide Feedback to Surgeon regarding physical location of Drill and Drill components • Select Surgical Phase • Set areas for mechanical restriction during surgical operation • Visualize CT Scanned Image with 2D Slices • Generate Panoramic reconstruction along arch • Visualize Panoramic reconstruction with cross sections along panoramic arch • Map Splint coordinate	No Changes

Feature	Subject Device: NGS with Yomi Plan v2.0	Predicate 1: NGS K161399	Predicate 2: Neocis Planning and Guidance Software for 3rd Party PCs K191363	Predicate 3: NGS with Edentulous Patient Splint K200805	SE Analysis
	system to structures in CT Scan • Define anatomical planes • Clip CT Scanned Images • Define Arch for generating panoramic reconstruction • Provide the user with a means to define a nerve • Allow the user to plan multiple implants • Measure distances and angles in the plan	system to structures in CT Scan • Define anatomical planes • Clip CT Scanned Images • Define Arch for generating panoramic reconstruction • Provide the user with a means to define a nerve • Allow the user to plan multiple implants • Measure distances and angles in the plan	• Allow the user to plan multiple implants • Measure distances and angles in the plan	system to structures in CT Scan • Define anatomical planes • Clip CT Scanned Images • Define Arch for generating panoramic reconstruction • Provide the user with a means to define a nerve • Allow the user to plan multiple implants • Measure distances and angles in the plan	
Level of Concern	Moderate	Moderate	Moderate	Moderate	Identical
Installation	Windows Installer .msi file	Executable file .exe	Windows Installer .msi file	Windows Installer .msi file	Upgrade to use Windows Installer
OTS Software	TeamViewer	N/A	N/A	N/A	Add TeamViewer
NGS Hardware	No changes (activate/use pre-existing network features)	See predicate 510(k) Summary	See predicate 510(k) Summary	See predicate 510(k) Summary	Identical
Wireless data transmission over LAN	Yes, via integrated hardware, tested according to: • AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. • IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence	N/A	N/A	N/A	Add wireless transmission of files over LAN
Interface	Windows based GIU	Windows based GIU	Windows based GIU	Windows based GIU	Updated look and organization

VII. Performance Testing

This submission only includes the planning software and wireless transmission coexistence.

Software V&V has been fully executed according to the following:

- ANSI AAMI ISO 14971: 2019 Medical devices - Applications of risk management to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- 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
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014

Wireless Coexistence was testing according to the following:

- AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.
- IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

- End User Validation testing was performed in a simulated use environment that is representative of the Surgical Environment and represents use with a patient to ensure that the system in its entirety, inclusive of design, manufacture, labeling, and processes developed for use meet the needs of the user, a validation activity will be performed.

VIII. Conclusion

This submission includes an update to our planning software and adds networking capabilities to the system. There are no technological changes to the hardware (NGS) in this submission. There are no changes to the intended use in this submission. There are no fundamental changes to the technology. Our performance testing demonstrates substantially equivalent performance of the subject device as compared to the predicate.