12/22/21

Neocis Inc.
William Tapia
VP, RA-QA
2800 Biscayne Blvd. Suite 600
Miami, Florida 33137

Re: K210711
Trade/Device Name: Neocis Guidance System (NGS) with Yomi Plan v2.0.1
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: November 24, 2021
Received: November 26, 2021

Dear William Tapia:

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 Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210711

Device Name
Neocis Guidance System (NGS) with Yomi Plan v2.0.1

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.

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."

510(k) Summary

K210711

I. Submitter

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

Contact Person: William Tapia, VP, RA-QA
Date Prepared: December 21, 2021

II. Device

Trade Name:	Neocis Guidance System (NGS) with Yomi Plan v2.0.1
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) with YomiPlan v2.0 (K202264)

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

[There is no device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. The NGS is not an In Vitro Diagnostic device.]
The purpose of subject device is for modification of the *Neocis Guidance System* (K202264) to allow for Wi-Fi to be continuously active in the Yomi Plan v2.0.1 while it is powered on. All other software and hardware features/functions remain identical to the predicate. 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) (Figure 1).
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.

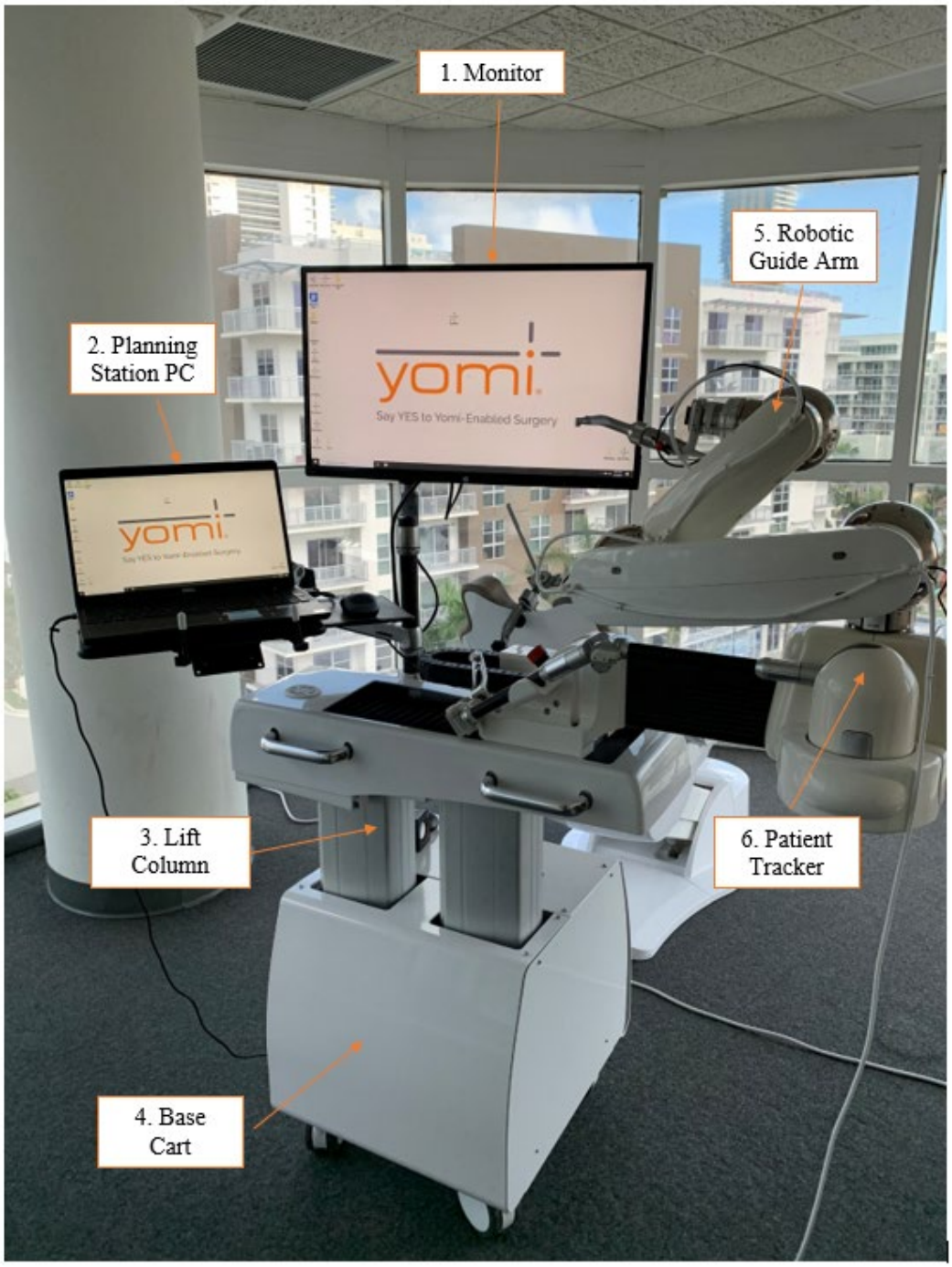

Figure 1. Overview of the Neocis Guidance System (NGS). Major components list below.

1. **Monitor:** Provides visibility of Yomi Plan for the user and operative team during a procedure. Displays the same information as the Planning station laptop PC

2. **Planning Station Laptop PC**: Used to execute Yomi Plan for planning and surgery. This PC is used during the procedure as well to execute commands for the Guide Arm. There is not separate keyboard. (Not intended for removal and use by itself for planning. Remote preplanning shall be executed on a different third party PC that is not connected to the NGS or provided by Neocis.)
3. **Lift Column:** Supports the Robotic Guide Arm and Patient Tracker assembly and is used to adjust the height of the assembly.
4. **Base Cart**: Supports the NGS, provides mobility with four swivel casters and locks in position with the foot brake lever. Contains control PC and UPS.
5. **Robotic Guide Arm:** Used to assist the surgeon in performing the surgery. Holds dental drill and provides haptic feedback on position with respect to the plan.
6. **Patient Tracker:** Attached to Patient Splint via the End Effector to monitor and relay any changes in patient position.

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. For partially edentulous patients, surgeons now have the option to use our new Clamped Chairside Patient Splint (CCPS) (K202100).

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 (Yomi Plan), is placed at the desired location in the virtual patient model within our planning software. The software highlights critical anatomical structures to avoid, such as the inferior alveolar nerve or maxillary sinuses. (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 powered bone cutting tool, 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 bone cutting tool's foot pedal control is not connect to the NGS guide arm. Once the guide arm places the bone cutting tool into position according to the operative plan, the surgeon must activate the tool using the provided foot pedal associated with the bone cutting tool control box. 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
- Automatic software-controlled safety pause triggered by joint or force limits
- Audio and visual queues
- Drill torque limits provided by the drill control console
- Full surgeon control and direct visualization of the surgical field

[There is no device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding the device description that is applicable to the subject device. The NGS is not an *In Vitro* Diagnostic device.]

VI. Comparison of Technological Characteristics

This submission is focused on an update to our planning software, Yomi Plan v2.0.1, which allows Wi-Fi to be continuously active while the system is powered on.

Table 1: Comparison of technological characteristics to the predicates

Feature	**Subject Device** **NGS with Yomi Plan v2.1** **K210711**	**Predicate Device** **NGS with Yomi Plan v2.0** **K202264**	**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 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).	Identical
Yomi Plan Software Version	v2.0.1	v2.0	Version change
OS	Windows 10	Windows 10	Identical
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 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.	Identical
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	• 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	Identical

Feature	Subject Device NGS with Yomi Plan v2.1 K210711	Predicate Device NGS with Yomi Plan v2.0 K202264	SE Analysis
	• Visualize CT Scanned Image with 2D Slices • Generate Panoramic reconstruction along arch • Visualize Panoramic reconstruction with cross sections along panoramic arch • Map Splint coordinate 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	• Visualize CT Scanned Image with 2D Slices • Generate Panoramic reconstruction along arch • Visualize Panoramic reconstruction with cross sections along panoramic arch • Map Splint coordinate 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	Identical
Installation	Windows Installer .msi file	Windows Installer .msi file	Identical
Origin	Proprietary	Proprietary	Identical
OTS Software	TeamViewer	TeamViewer	Identical
NGS Hardware	No changes (activate/use pre-existing network features)	No changes (activate/use pre-existing network features)	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	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	Identical
Interface	Windows based GIU	Windows based GIU	Identical
Wi-Fi	Always active	Disabled during osteotomy	Disabled Wi-Fi no longer a safety mitigation

VII. Performance Testing

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

Software verification testing 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
- Postmarket Management of Cybersecurity in Medical Devices Document issued on December 28, 2016.
- Cybersecurity for Networked Medical Devices Containing Off the-Shelf (OTS) Software

Document issued on: January 14, 2005.

- AAMI TIR57: 2016 Principles For Medical Device Security - Risk Management Wireless

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

EMC testing was conducted according to the following:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

VIII. Conclusion

This submission includes an update to our planning software that enables Wi-Fi to be active continuously while the system is powered on. There are no technological changes to the hardware (NGS) or software in this submission. There are no changes to the intended use or the indications for 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.