Neocis, Inc.   October 10, 2025
Jorge Fernandes
VP Quality and Regulatory
545 NW 26th Street
Miami, Florida 33127

Re: K251835
    Trade/Device Name: Yomi Robotic System
    Regulation Number: 21 CFR 872.4120
    Regulation Name: Bone Cutting Instrument And Accessories
    Regulatory Class: Class II
    Product Code: PLV, QRY
    Dated: June 13, 2025
    Received: September 19, 2025

Dear Jorge Fernandes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Andrew I. Steen -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251835	?

Please provide the device trade name(s).	?

Yomi Robotic System

Please provide your Indications for Use below.	?

The Yomi Robotic System (Yomi) is a computerized robotic 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 robotic navigational guidance of the surgical instruments. The system can also be used for planning and performing guided bone reduction (also known as alveoplasty) of the mandible and/or maxilla. Yomi is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

When YomiPlan 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 using the Yomi Robotic System. The output of Yomi Plan is to be used with the Yomi Robotic System.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary K251835

I.   Submitter

Neocis, Inc.
545 NW 26th Street
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Miami, FL 33127
Tel: 1-855-9NEOCIS

Contact Person:	Jorge Fernandes, VP, QA-RA
Date Prepared:	October 10, 2025

Device

Trade Name:	Yomi Robotic System
Common Name:	Dental Stereotaxic Instrument
Classification Name:	Bone cutting instrument and accessories (21 CFR 872.4120)
Classification:	Class II
Product Code:	PLV, QRY

Predicate Devices

Primary Predicate: Yomi Robotic System (K231018)
Reference Device: Relu Creator (K233925)

Indications for Use

The Yomi Robotic System (Yomi) is a computerized robotic 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 robotic navigational guidance of the surgical instruments. The system can also be used for planning and performing guided bone reduction (also known as alveoplasty) of the mandible and/or maxilla. Yomi is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

When YomiPlan 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 using the Yomi Robotic System. The output of Yomi Plan is to be used with the Yomi Robotic System.

Device Description

Yomi Robotic System is a dental stereotaxic instrument and a powered surgical device for bone cutting. Yomi Robotic System 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 Yomi Robotic System is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants.

The Yomi Robotic System allows the user to plan the surgery virtually in YomiPlan, 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 the planning software. The plan is used for the system to provide physical, visual, and audible feedback to the

surgeon during the implant site preparation. The Yomi robotic arm holds and guides a standard FDA-cleared third party powered bone cutting instrument.

The patient tracking portion of Yomi is comprised of linkages from the patient to Yomi, which include the Patient Splint (YomiLink Teeth or YomiLink Bone), Tracker End Effector (TEE), and the Patient Tracker (PT). In cases where YomiLink Teeth is utilized, it is attached to the contralateral side of the patient's mouth over stable teeth using on-label dental materials prior to the presurgical CBCT scan. In cases where YomiLink Bone is utilized, it is placed using bone screws prior to the presurgical CBCT scan (appropriate local anesthesia is required), or after the scan when using the subject YomiLink Arch device.

The subject of this submission is to: Integrating algorithms that provide automatic segmentation of maxillary sinuses, inferior alveolar nerve, and maxillary and mandibular bone. The integrated software, Relu Creator, was cleared in K233925. The software is not adaptive, it is trained at the manufacturer (Relu), and the weights are locked.

Additionally, since the most recent clearance of Yomi Robotic System (K231018), minor modifications to the Yomi System include the following:

- Planning software improvements
    - Restorative planning – Features to support customized crown design
    - Dual arch planning – Feature to enable the end user to plan multiple arches in a singe case and a singe scan
    - Patient work volume guidance improvements – Added guidance for the angulation of the patient chair
    - Added patient proximity for baseline
    - YomiLink Bone (YLB) planning – improved placement of the YLB
    - Added proximity threshold lower limit value
    - Improved alignment between CT scans and imported .stl objects
    - Added ability for user to designate soft tissue thickness to assist in bone reduction planning
    - Added max depth information to the implant cursor hover info
    - VTK Off-the-Shelf software version update
    - Added model details to implant selection
    - Added restorative planning case feedback option
    - Added additional implant models to the implant library
- Control software and behavior improvements
    - Updates to handpiece interaction gestures, and optimization of the response of the control software to guide arm joint limits, singularities and potential wrist / base collisions.
- Hardware improvements Tracker Arm Joint
- Accessory improvements
    - Updates to the YomiLink Teeth and intraoral fiducial array
- Minor bug fixes

All other aspects of the Yomi Robotic System remain unchanged from prior clearances.

Comparison of Technological Characteristics

The following Table 1 provides a summary of the subject Yomi Robotic System features compared to the predicate device, Yomi Robotic System (K231018) and reference device Relu Creator (K233925

Table 1: Comparison of technological characteristics to the predicate (with a supporting reference device)

Feature	Subject Device: Yomi Robotic System with Automatic Segmentation Algorithm	Primary Predicate: Yomi Robotic System with YomiLink Arch K231018	Reference Device: Relu Creator (K233925)	Justification of Differences
Device Name	Yomi Robotic System	Yomi Robotic System	Relu Creator	Equivalent
Device Classification	Class II	Class II	Class II	Equivalent
Indications for use	The Yomi Robotic System (Yomi) is a computerized robotic 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 robotic navigational guidance of the surgical instruments. The system can also be used for planning and performing guided bone reduction (also known as alveoplasty) of the mandible and/or maxilla. Yomi is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants. When YomiPlan software is used for preplanning on third-party PCs, it is intended to perform the planning (pre-operative) phase of dental implantation surgery. YomiPlan provides preoperative planning for dental implantation procedures using the Yomi Robotic System. The output of YomiPlan is to be used with the Yomi Robotic System.	Yomi Robotic System is a computerized robotic 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 robotic navigational guidance of the surgical instruments. The system can also be used for planning and performing guided bone reduction (also known as alveoplasty) of the mandible and/or maxilla. Yomi Robotic System is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants. When YomiPlan software is used for preplanning on third-party PCs, it is intended to perform the planning (pre-operative) phase of dental implantation surgery. YomiPlan provides preoperative planning for dental implantation procedures using the Yomi Robotic System. The output of YomiPlan is to be used with the Yomi Robotic System.	Relu Creator is a software program for the management, transfer, and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations. .	Equivalent The subject device has the same Indications for Use as the predicate device. The Reference device is a software application that is part of the digital workflow of dental specialists in preoperative planning.
Intended User	Dentist	Dentist	Dentist	Equivalent
Use environment	Clinical Setting, Doctors Office	Clinical Setting, Doctors Office	N/A	Equivalent
Yomi Plan Software Version	v2.7	v2.4.1	N/A	Equivalent The only difference is a version change due to the addition of Automatic Segmentation Algorithm functionality and minor LTF changes since the last K231018 clearance. All changes have been successfully verified and, therefore, not considered to affect the overall safety and efficacy profile of Yomi Plan.

Feature	Subject Device: Yomi Robotic System with Automatic Segmentation Algorithm	Primary Predicate: Yomi Robotic System with YomiLink Arch K231018	Reference Device: Relu Creator (K233925)	Justification of Differences
OS	Windows 10	Windows 10	Windows 10 or 11	Equivalent
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.	Windows 10 or 11 with minimum 8 GB of RAM and Intel i5 or Ryzen 5 with Nvidia GPU 4GB VRAM (with CUDA drivers of at least 450.80.02 on Linux and 452.39 on Windows) using Pascal architecture or newer, Ubuntu 20.04 or newer (or an equivalent distribution with glibc 2.28 or newer) Client Hosted Servers: Ubuntu 20.04 or newer (or an equivalent distribution with glibc 2.28 or newer)	Equivalent The software has been successfully verified to perform with the PC specifications of the Yomi Robotic System. Therefore, the difference is considered not to affect the overall safety and efficacy profile of Yomi Plan.
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 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 - Integrated Automatic Segmentation Algorithm.	- 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 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	The Relu Creator is a software that is part of the digital workflow of dental specialists in preoperative planning. The main purpose is the 3D modeling of the patient anatomy, which is technically called image segmentation and multimodel registration. Based on the model, simulations for preoperative and pretreatment planning can be carried out for dental applications. The 3D modeling (segmentation + registration) is performed on medical images like CBCT, IOS and FS. The preoperative/pretreatment software can be applied in various dental disciplines such as orthodontics, implantology, and maxillofacial surgery.	Equivalent The only change is the addition of Automatic Segmentation Algorithm functionality. Yomi Plan 2.7 with Automatic Segmentation Algorithm functionality was successfully verified and user validated.
Software Level of Concern	Enhanced	Enhanced	N/A	Equivalent
Installation	Windows Installer .msi file	Windows Installer .msi file	N/A	Equivalent

Feature	Subject Device: Yomi Robotic System with Automatic Segmentation Algorithm	Primary Predicate: Yomi Robotic System with YomiLink Arch K231018	Reference Device: Relu Creator (K233925)	Justification of Differences
Origin	Proprietary	Proprietary	3rd Party	Equivalent
Software	TeamViewer	TeamViewer	Relu® Engine	Equivalent
Yomi Hardware	No changes (activate/use pre-existing network features)	No changes (activate/use pre-existing network features)	N/A	Equivalent
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	N/A	Equivalent
Interface	Windows based GIU	Windows based GIU	Windows based GIU	Equivalent
Wi-Fi	Always active	Always active	N/A	Equivalent

Performance Testing

Software and Cybersecurity Verification and Validation Testing

- Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" published (June 2023). The software for this device was considered an "enhanced" level of concern, since a failure or latent flaw in the software could directly result in result in minor injury to the patient or operator.
- Software Development and Testing was performed per IEC 62304 Edition 1.1 2015 Medical Device Software – Software Lifecycle Processes, FDA Guidance for the Content of Premarket Submissions for Device Software Functions (June 2023), and FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 2002). The combined testing and analysis of results provides assurance that the device performs as intended.
- Cybersecurity development and testing was performed in accordance with FDA's Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025) and Postmarket Management of Cybersecurity in Medical Devices (December 2016).

User Validation testing

Usability validation testing has been performed in accordance with the FDA Guidance document "Applying Human Factors and Usability Engineering to Medical Devices" Final Guidance, (February 2016).

Conclusion

The subject of this submission is to modify the software to include automatic segmentation of maxillary sinuses, inferior alveolar nerve, and maxillary and mandibular bone, as well as minor modifications including planning software improvements, control software and behavior improvements, hardware improvements – Tracker Arm Joint, accessory improvements and minor bug fixes. There are no changes to the intended use compared to the predicate device. There are no fundamental changes to the technology. The performance testing demonstrates substantially equivalent performance of the subject device as compared to the predicate.