November 4, 2022

Neocis Inc.
Olga Lewis
Regulatory Affairs Director
2800 Biscayne Blvd
Suite 600
Miami, Florida 33137

Re: K222049
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: QRY, PLV
Dated: October 13, 2022
Received: October 17, 2022

Dear Olga Lewis:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE.
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)*
K222049

Device Name
Yomi Robotic System

Indications for Use *(Describe)*
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 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.

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

K222049

I. Submitter

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Suite 600
Miami, FL 33137
Tel: 1-855-9NEOCIS

Contact Person: Olga Lewis, Director of Regulatory Affairs
Date Prepared: November 3, 2022

II. Device

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

III. Predicate Devices

Primary Predicate: Neocis Guidance System (NGS) with Yomi Plan v2.0.1 K210711
Reference Device: Mako Partial Knee Application K142530

IV. Indications for Use

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 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.

V. Device Description

In terms of FDA regulations, the *Yomi Robotic System* 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 (K210711), the *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 System* allows the user to plan the surgery virtually in Yomi Plan, 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 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 Chairside Patient Splint (CPS) or Edentulous Patient Splint (EPS), 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 prior to the presurgical CBCT scan. The EPS is placed using bone screws prior to the presurgical CBCT scan (appropriate local anesthesia is required).

The subject of this submission is introducing a feature to allow the system to be used for planning and performing guided bone reduction (also known as alveoplasty). The bone reduction feature is intended for use during dental implant procedures to flatten the surface of the bone intended for dental implant placement. The device is used with compatible bone cutting tool secured to the guidance arm for the bone reduction. The bone reduction feature is intended to be performed on full arch or partially edentulous patients. During preoperative planning, the surgeon identifies the area of the bone to be reduced. Real-time visualization of the bone reduction is visualized on the graphic user interface. The guidance arm constrains the movement of the cutting tool to the planned location, boundaries, and depth. After the bone reduction, the implant procedure continues with the Yomi Robotic System.

VI. Comparison of Technological Characteristics

The following Table 1 provides a summary of the subject Yomi System features compared to the predicate device, Neocis Guidance System (NGS) with Yomi Plan v2.0.1 (K210711), and a reference device, Mako Partial Knee Application (K142530). The MAKO device was chosen as the reference device since the visualization method during bone removal with the MAKO system for PKA is essentially the same as the subject device. Although the indications for use are different, the implementation of the visualization of the bone removal process is equivalent with both, the reference device as well as the predicate device.

Table 1: Comparison of technological characteristics to the predicates

Technological Characteristics	Subject Device: Yomi Robotic System with Yomi Robotic Guided Bone Reduction	Primary Predicate: Neocis Guidance System (NGS) with Yomi Plan v2.0.1 K210711	Reference Device: Mako Partial Knee Application K142530	Comparison
Indications for Use (IFU)	*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 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*.	Neocis Guidance System (NGS*)* 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 NGS 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 pre-operative planning for dental implantation procedures using the *NGS*. The output of Yomi Plan is to be used with the *NGS*.	The Partial Knee Application (PKA), for use with the Robotic Arm Interactive Orthopedic System (RIO), is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures. The Partial Knee Application (PKA), for use with the Robotic Arm Interactive Orthopedic System (RIO), is indicated for use in surgical knee procedures in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include unicondylar knee replacement and/or patellofemoral knee replacement. The Implant systems with which the system is compatible: -Restoris Multicompartmental Knee System -Restoris Porous Partial Knee System	When compared to the primary predicate device, K210711, added text specific to bone reduction. Reference device has different indications but overall is equivalent since it offers power tools and software modifications for bone cutting.

Technological Characteristics	Subject Device: Yomi Robotic System with Yomi Robotic Guided Bone Reduction	Primary Predicate: Neocis Guidance System (NGS) with Yomi Plan v2.0.1 K210711	Reference Device: Mako Partial Knee Application K142530	Comparison
Robotic Guide Arm	Guided robotic arm	Guided robotic arm	Guided robotic arm	Equivalent
Movement Direction	Guided Robotic Arm holds a surgical instrument and provides haptic feedback on position with respect to the plan restricting movement outside of volume predefined during planning. 6 degrees of freedom	Guided Robotic Arm holds a surgical instrument and provides haptic feedback on position with respect to the plan restricting movement outside of volume predefined during planning. 6 degrees of freedom	Guided Robotic Arm holds a surgical instrument and provides haptic feedback on position with respect to the plan restricting movement outside of volume predefined during planning. 6 degrees of freedom	Equivalent
Patient affixed tracking parts	Splints with arrays	Splints with arrays	Femoral and tibial tracking arrays affixed to bones during surgery	Equivalent
Patient Tracking Mechanism	Physical linkage to patient via Patient Tracker (PT), Kinematic Mount (KM), and End Effector (EE) connected to splints	Physical linkage to patient via Patient Tracker (PT), Kinematic Mount (KM), and End Effector (EE) connected to splints	Optical IR camera used for tracking femoral and tibial arrays	Equivalent
Fiducials for CT scan	Fiducial Array (FA) attached to splint	Fiducial Array (FA) attached to splint	Fiducials	Equivalent
Powered Handpiece	Handpiece and drills	Handpiece and drills	Anspach Black Max bone cutting system	Equivalent
Cutting tools	Burs and drills	Drills and burs	Burs	Equivalent
Planning and Guidance Software	Updated Yomi Plan and NeoK software to support bone reduction feature (Windows-based)	Yomi Plan software used for planning and osteotomy (Windows-based)	Linux-based software application used for planning and bone preparation	Equivalent
Workflow	Surgeon plans bone reduction and implant placement and executes according to the plan following steps displayed on	Surgeon plans implant placement and executes according to the plan following steps displayed on	Surgeon plans surgical procedure, including bone cutting and implant placement, and executes according to the	Equivalent

Technological Characteristics	Subject Device: Yomi Robotic System with Yomi Robotic Guided Bone Reduction	Primary Predicate: Neocis Guidance System (NGS) with Yomi Plan v2.0.1 K210711	Reference Device: Mako Partial Knee Application K142530	Comparison
	the GUI	the GUI	plan following steps displayed on the GUI	
Visualization of Bone Removal	Bone to be removed is colored and during removal, the color of the bone on the screen is updated (in real time) to another color to reflect bone removal.	N/A	Bone to be removed is colored and during removal, the color of the bone on the screen is updated (in real time) to another color to reflect bone removal.	Equivalent
Performance Testing	Unit Level Testing Integration and regression testing Verification testing of the new handpiece and bur Verification of bone reduction planning, visualization, and performance Bone reduction accuracy verification Full system cadaver validation	Unit Level Testing Integration and regression testing Verification testing of compatible instrumentation Verification of osteotomy planning, visualization, and performance Osteotomy accuracy verification Full system cadaver validation	Sub-system level software functional testing of Setup and Bone Preparation Implant visuals, boundaries and stereotactic verification Resection accuracy verification Full system mock procedure run-through verification Full system cadaver validation	Equivalent

VII. Performance Testing

Software verification testing has been fully executed to ensure that the software user interface functions as intended 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
- Guidance for Industry and FDA Staff General Principles of Software Validation Document issued on: January 11, 2002

Additionally, verification testing for new instruments used in bone reduction procedures has been performed with the Yomi System along with validation testing, including cadaveric Human Factors Validation for Bone Reduction and Software End User Validation of Bone Reduction.

VIII. Conclusion

This submission introduces a bone reduction feature to the *Yomi Robotic System.* 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.