Neocis Inc.
Joshua Davis
Regulatory Affairs Manager
2800 Biscayne Blvd Suite 600
Miami, Florida 33137

December 8, 2022

Re: K222750
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: September 29, 2022
Received: September 30, 2022

Dear Joshua Davis:

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,

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

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)*
K222750

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. YomiPlan provides pre-operative planning for dental implantation procedures using the Yomi Robotic System. The output of YomiPlan 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.

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

K222750

I. Submitter

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

Contact Person: Joshua Davis, Regulatory Affairs Manager
Date Prepared: December 7, 2022

II. 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: QRY, PLV

III. Predicate Devices

Primary Predicate: Yomi Robotic System (K222049)
Reference Device: Neocis Guidance System (K191605)
Reference Device: Neocis Guidance System (K161399)
Reference Device: Resert XL HD High-Level Disinfectant (K091022)

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. YomiPlan provides pre- operative planning for dental implantation procedures using the Yomi Robotic System. The output of YomiPlan is to be used with the Yomi Robotic System.

V. 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 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 Clamped Chairside Patient Splint (C-CPS) or YomiLink Bone (YLB), the Tracker End Effector (TEE) 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 to modify the design and reprocessing method for the Tracker End Effector (TEE) of the Yomi Robotic System. All other aspects of the Yomi Robotic System remain unchanged from prior clearances.

VI. 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 (K222049).

Table 1: Comparison of technological characteristics to the predicate

Technological Characteristics	Subject Device: Yomi Robotic System	Primary Predicate: Yomi Robotic System (K222049)	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. YomiPlan provides pre-operative 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 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.	Equivalent
Principles of Operation	The Tracker End Effector physically attaches to, and provides linkage between, the Patient Tracker of the Yomi Robotic System and the Patient Splint. The Tracker End Effector is connected to the Patient Tracker via a screw at the Patient Tracker Flange. The	The Tracker End Effector physically attaches to, and provides linkage between, the Patient Tracker of the Yomi Robotic System and the Patient Splint. The Tracker End Effector is connected to the Patient Tracker via a screw at	Equivalent

Technological Characteristics	Subject Device: Yomi Robotic System	Primary Predicate: Yomi Robotic System (K222049)	Comparison
	Tracker End Effector is then also connected via screw to the Patient Splint.	the Patient Tracker Flange. The Tracker End Effector is then also connected via screw to the Patient Splint.	
Robotic Guide 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	Equivalent
Patient affixed tracking parts	Splints with arrays	Splints with arrays	Equivalent
Patient Tracking Mechanism	Physical linkage to patient via Patient Tracker (PT), Kinematic Mount (KM), and Tracker End Effector (TEE) connected to splints	Physical linkage to patient via Patient Tracker (PT), Kinematic Mount (KM), and Tracker End Effector (TEE) connected to splints	Equivalent
Fiducials for CT scan	Fiducial Array (FA) attached to splint	Fiducial Array (FA) attached to splint	Equivalent
Patient Contact	No contact	No contact	Equivalent
Reprocessing Classification	Non-critical	Non-critical	Equivalent
Reprocessing Method for Tracker End Effector	High level disinfection	Sterilization	Equivalent Disinfection validation testing has demonstrated disinfection of the subject device provides adequate microbicidal reprocessing
Mating Component Design	V-coupled design	Fiducial pins and spheres	Equivalent Verification testing has demonstrated the modified design has no impact on

Technological Characteristics	Subject Device: Yomi Robotic System	Primary Predicate: Yomi Robotic System (K222049)	Comparison
			substantial equivalence
Materials	TEE main body: Aluminum 7075 TEE thumb screws: Stainless Steel 316	TEE main body: Aluminum 6061 TEE thumb screws: Stainless Steel 316	Equivalent Verification testing has demonstrated the modified material has no impact on substantial equivalence
Performance Testing	Total System Accuracy Kinematic Mount Repeatability Drill Jig Accuracy Disinfection Validation Reprocessing Instruction Validation	Total System Accuracy Kinematic Mount Repeatability Drill Jig Accuracy	Equivalent

VII. Performance Testing

The following testing has been fully executed to ensure that the subject device functions as intended:

- Total System Accuracy Verification
- Kinematic Repeatability Verification
- Drill Jig Accuracy Verification
- High-Level Disinfection Validation was performed in accordance with recommended evaluations as listed in AAMI TIR12 and Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Usability validation testing for the modified reprocessing instructions has been performed. Usability testing included dental clinician users who were evaluated on critical tasks for the disinfection steps per the disinfection instructions for use and provided responses to open-ended questions.

VIII. Conclusion

This subject of this submission is to modify the design and reprocessing method for the Tracker End Effector (TEE) of 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.