August 14, 2023

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

Re: K231018
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: July 13, 2023
Received: July 14, 2023

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)*
K231018

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 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 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.

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510(k) Summary
K231018

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: August 14, 2023

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 and Reference Devices

Primary Predicate: Yomi Robotic System (K222750)
Reference Device: Yomi Robotic System (K211129)

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 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 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 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 introduce new accessories, the YomiLink Arch and Probing Bit. The YomiLink Arch allows for CBCT scan acquisition prior to YomiLink Bone placement and enables guided YomiLink Bone placement. This submission also introduces an update to the system planning software to enable use of the YomiLink Arch (YLA).

Following attachment of YomiLink Bone (YLB) to the patient, probing of the YLA is performed utilizing the YLA Probing Bit to transfer registration in the software from YLA to YLB and allow for tracking of the YLB throughout the remaining surgical procedure. The YLA Probing Bit is available in straight and contra-angle configurations corresponding to the handpiece to which they are attached.

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 (K222750), and reference device, Yomi Robotic System (K211129).

Table 1: Comparison of technological characteristics to the predicate and reference devices.

Technological Characteristics	Subject Device: Yomi Robotic System with YomiLink Arch	Primary Predicate: Yomi Robotic System with Intraoral Fiducial Array (K222750) & Reference Device: Yomi Robotic System (K211129)	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 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 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

Technological Characteristics	Subject Device: Yomi Robotic System with YomiLink Arch	Primary Predicate: Yomi Robotic System with Intraoral Fiducial Array (K222750) & Reference Device: Yomi Robotic System (K211129)	Comparison
Principles of Operation	YomiLink Arch contains fiducial markers that allow for registration in CBCT scans prior to surgery. The Tracker End Effector is attached to YomiLink Arch to provide a connection between the patient and the Patient Tracker arm of the system. YomiLink Arch contains divots that can then be probed with the robot to match to known locations in the CBCT scan image space based on the fiducial markers	The Intraoral Fiducial Array contains fiducial markers that allow for registration in CBCT scans prior to surgery. The Intraoral Fiducial Array mounts to the YomiLink Teeth patient splint	Equivalent
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	YomiLink Arch Splints	Splints with arrays	Equivalent
Patient Tracking Mechanism	Physical linkage to patient via Patient Tracker (PT), Kinematic Mount (KM), and Tracker End Effector (TEE)	Physical linkage to patient via Patient Tracker (PT), Kinematic Mount (KM), and Tracker End Effector (TEE)	Equivalent
Fiducials for CT scan	YomiLink Arch contains fiducial beads and is placed directly on patient arch during the CT scan to provide a reference in the image	Intraoral Fiducial Array contains fiducial beads and is attached to patient splint during the CT scan to provide a reference in the image	Equivalent

Technological Characteristics	Subject Device: Yomi Robotic System with YomiLink Arch	Primary Predicate: Yomi Robotic System with Intraoral Fiducial Array (K222750) & Reference Device: Yomi Robotic System (K211129)	Comparison
Probing Bit	YLB is registered by probing the YLA divots	N/A. YLB is registered via CT scan	Equivalent
Patient Contact	Surface device Limited duration	Surface device Limited duration	Equivalent
Biocompatibility	Mucosal membrane, tissue, bone, dentin contact	Mucosal membrane, tissue, bone, dentin contact	Equivalent
Reprocessing Classification	N/A. Single use only	Non-critical reusable	Equivalent
Reprocessing Method	N/A. Single use only. Sterilized by the end user prior to use	Cleaning & Sterilization	Equivalent
Sterilization Method	Provided unsterile, end user moist heat sterilized	Provided unsterile, end user moist heat sterilized	Equivalent
Mating Component Design	Kinematic Mount	Kinematic Mount	Equivalent
Materials	Main body: Avaspire AV-651 CF30 Fiducial Beads: Silicon Nitride Epoxy: EA M-31CL epoxy Probing Bit: 17-4 Stainless Steel, Precipitation Hardened (PH)	Main body: Avaspire AV-651 CF30 Fiducial Beads: Silicon Nitride Epoxy: EA M-31CL epoxy	Equivalent
Performance Testing	• Total System Accuracy Verification • Probing and Registration Verification • Deflection and Repeatability Verification • Guided Splint Placement Verification • Proximity Warnings Verification • Typical Run Through Verification • Human Factors Validation • Software End User Validation	• Total System Accuracy Verification • Registration Verification • Deflection and Repeatability Verification • Human Factors Validation	Equivalent

VII. Performance Testing

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

- Total System Accuracy Verification: to verify the accuracy of the full system with the additional YLA workflow
- Guided Splint Placement Verification: to verify the accuracy of guided splint placement as part of the YLA workflow
- Probing and Registration Verification: to verify the accuracy of probing the YLA
- Deflection and Repeatability Verification: to assess the stability and repeatability of attachment of the YLA
- Proximity Warnings Verification: to assess the proximity warnings generated in the user application throughout the YLA workflow
- Typical Run Through Verification: to assess the typical steps in the user application throughout the YLA workflow
- Human Factors Validation: to validate the human factors and design of the YLA
- Software End User Validation: to validate that the YLA user application meets the user requirements

Non-clinical data referenced or relied upon for the subject YomiLink Arch and Probing Bit from the predicate, K222750, to demonstrate substantial equivalence include: Biocompatibility testing per the FDA Guidance Document for Use of Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and validated cleaning & sterilization instructions per FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" and ISO 17665-1 and ISO 17665-2.

VIII. Conclusion

The subject of this submission is to introduce new accessories, the YomiLink Arch and Probing Bit, which allow for CBCT scan acquisition prior to YomiLink Bone placement and enables guided YomiLink Bone placement. This submission also introduces an update to the system planning software to enable use of the YomiLink Arch. 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.