October 28, 2025

Neocis, Inc.
Jorge Fernandes
Vice President of Quality and Regulatory
545 NW 26th Street
Suite 700
Miami, Florida 33127

Re: K252376
Trade/Device Name: Yomi S 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 30, 2025
Received: September 30, 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,

MICHAEL E. ADJODHA -S

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

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.	K252376

Please provide the device trade name(s).

Yomi S Robotic System

Please provide your Indications for Use below.

The Yomi S Robotic System (Yomi S) 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 S 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 S Robotic System. The output of YomiPlan is to be used with the Yomi S 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

K252376

I. Submitter

Neocis, Inc.
545 NW 26th Street
Unit 700
Miami, FL 33127
Tel: 1-855-9NEOCIS

Contact Person: Jorge Fernandes, VP, QA-RA
Date Prepared: October 24, 2025

Device

Trade Name: Yomi S 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)

Indications for Use

The Yomi S Robotic System (Yomi S) 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 S 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 S Robotic System. The output of YomiPlan is to be used with the Yomi S Robotic System.

Device Description

The Neocis Yomi S is a modified next iteration of the Yomi Robotic System, designed to provide guidance for a dental surgeon during dental implant surgery. Yomi S is a dental stereotaxic medical device (Product Codes PLV, QRY) regulated under21 CFR 872.4120. The device includes a YomiLink that is placed on the patient prior to the CT scan, and a fiducial array with fiducial markers that is placed on the YomiLink prior to the CT scan so the virtual plan can be related to the physical space of the system. The Guidance Arm secures a standard dental drill, allowing the surgeon to grip the drill as normal. The Guidance Arm does not move unless the surgeon applies a manual force to the drill. The Guidance Arm will constrain the surgeon to drill according to the prescribed surgical plan, preventing deviation. The surgeon is constantly in control of the drilling. The system has a mechanical feedback system that is connected to the YomiLink on the patient, which relays information to the control software 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 and position to accommodate the patient movement, which will maintain the accuracy of the drill placement.

The Yomi S 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 S robotic arm holds and guides a standard FDA- cleared third party powered bone cutting instrument.

The patient tracking portion of Yomi S is comprised of linkages from the patient to Yomi S, 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 the Yomi S Robotic System, a next-generation modification of the Yomi Robotic System, intended to assist dental surgeons by providing guidance during dental implant procedures.

Comparison of Technological Characteristics

The following Table 1 provides a summary of the subject Yomi S Robotic System features compared to the predicate device, Yomi Robotic System (K231018).

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

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
Use Specifications			
Indications for Use (IFU)	The Yomi S Robotic System (Yomi S) 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 S 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 S Robotic System. The output of YomiPlan is to be used with the Yomi S 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 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.	Equivalent
Principles of Operation	*Yomi S* is a dental stereotaxic medical device (Product Codes PLV, QRY) and a powered surgical device for bone cutting (21 CFR 872.4120). *Yomi S* is a computerized navigational system intended to	*Yomi Robotic System* is a dental stereotaxic medical device (Product Codes PLV, QRY) and a powered surgical device for bone cutting (21 CFR 872.4120). *Yomi Robotic System* is a computerized navigational	Equivalent

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
	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 S* is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants. The device includes a Patient Splint that is placed on the patient prior to the CT scan, and a fiducial array with fiducial markers that is placed on the Patient Splint prior to the CT scan so the virtual plan can be related to the physical space of the system. The Guidance Arm secures a standard dental drill, allowing the surgeon to grip the drill as normal. The Guidance Arm does not move unless the surgeon applies a manual force to the drill. The Guidance Arm will constrain the surgeon to drill according to the prescribed surgical plan, preventing deviation. The surgeon is constantly in control of the drilling. The system has a mechanical feedback system that is connected to the Patient Splint on the patient, which relays information to the control software 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 and position to accommodate the patient movement, which will	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 device includes a Patient Splint that is placed on the patient prior to the CT scan, and a fiducial array with fiducial markers that is placed on the Patient Splint prior to the CT scan so the virtual plan can be related to the physical space of the system. The Guidance Arm secures a standard dental drill, allowing the surgeon to grip the drill as normal. The Guidance Arm does not move unless the surgeon applies a manual force to the drill. The Guidance Arm will constrain the surgeon to drill according to the prescribed surgical plan, preventing deviation. The surgeon is constantly in control of the drilling. The system has a mechanical feedback system that is connected to the Patient Splint on the patient, which relays information to the control software 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 and position to accommodate the	

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
	maintain the accuracy of the drill placement.	patient movement, which will maintain the accuracy of the drill placement.	
Use Environment	Clinical Setting, Doctor's Office	Clinical Setting, Doctor's Office	Equivalent
Technology / Performance Characteristics			
Pre-Operative Planning	The dentist places the virtual implant images in the desired location and orientation on the Yomi S Application software, which displays the patient's CT information in 3 dimensions. The precise location, angulations and type of virtual implant are determined based on the intermaxillary relations, bone structure and width, and adjacent critical anatomical structures.	The dentist places the virtual implant images in the desired location and orientation on the Yomi Robotic System Application software, which displays the patient's CT information in 3 dimensions. The precise location, angulations and type of virtual implant are determined based on the intermaxillary relations, bone structure and width, and adjacent critical anatomical structures.	Equivalent
Intra-Operative Setup	The Yomi S dental handpiece is autoclave sterilized and the Patient Tracker End-Effector is high-level disinfected or sterilized. The end-effectors are attached to their respective arms and the system is draped on both arms with single-use, non-sterile drapes. A single-use barrier film protects the column controls. The User Interface monitor, monitor handles, and cart handles are Intermediate-level disinfected. All other components of the system are subject to general cleaning using an intermediate-level disinfectant wipe.	The Yomi Robotic System dental handpiece is autoclave sterilized and the Patient Tracker End-Effector is high-level disinfected or sterilized. The end-effectors are attached to their respective arms and the system is fully draped with single-use, non-sterile drapes.	Equivalent. All high touch points have been assessed and the applicable level of disinfection determined and validated The testing has shown that the device is as safe and effective as the predicate.
Intra-Operative Process	The registration is completed during pre-operative steps, identification of the fiducials (Extra Oral Fiducial Array (EOFA) and Intra Oral Fiducial Array (IOFA)) in the software. The Patient Tracker is attached to the	The registration is completed during pre-operative steps, identification of the fiducials (Extra Oral Fiducial Array (EOFA) and Intra Oral Fiducial Array (IOFA)) in the software. The Patient Tracker is attached to the	Equivalent

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
	YomiLink to complete the link between the image and the patient. Using the Yomi S System guidance, the surgeon approaches the site of surgery following the audible, visual, and physical cues given by the system. The surgical implantation procedure is performed by the dentist as guided by the system, in line with preoperative planning. During the surgical procedure, the Yomi S guidance will warn and attempt to prevent any deviation between the planned location and the actual performance. The warnings are visual, audible, and physical.	YomiLink to complete the link between the image and the patient. Using the YRS System guidance, the surgeon approaches the site of surgery following the audible, visual, and physical cues given by the system. The surgical implantation procedure is performed by the dentist as guided by the system, in line with preoperative planning. During the surgical procedure, the YRS guidance will warn and attempt to prevent any deviation between the planned location and the actual performance. The warnings are visual, audible, and physical.	
Robotic Guide Arm	Guided robotic arm with 7 degrees of freedom	Guided robotic arm with 6 degrees of freedom	Equivalent The subject device provides an additional degree of freedom that is intended to provide additional dexterity and address the occurrence of singularities and joint limits. Testing has been performed to show device is as safe and effective as the predicate.
Movement Direction	Guided Robotic Arm holds a surgical instrument and provides haptic feedback on position with respect to the plan restricting movement	Guided Robotic Arm holds a surgical instrument and provides haptic feedback on position with respect to the plan restricting movement	Equivalent The subject device provides an additional

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
	outside of volume predefined during planning. 7 degrees of freedom	outside of volume predefined during planning. 6 degrees of freedom	degree of freedom that is intended to provide additional dexterity and address the occurrence of singularities and joint limits. Testing has been performed to show device is as safe and effective as the predicate.
Patient affixed tracking parts	YomiLink Arch YomiLink Bone Yomi Link Teeth	YomiLink Arch YomiLink Bone Yomi Link Teeth	Equivalent
Mating Component Design	Kinematic Mount with threaded metal insert and larger screw thread size	Kinematic Mount with tapped hole and smaller screw thread size	Equivalent. The subject device contains a larger thread for usability and a threaded metal insert to reduce the frequency of cross-threading. Testing has been performed to show that the device as is safe and effective as the predicate.
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

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
Visualization	CT Scanned Image (DICOM)	CT Scanned Image (DICOM)	Equivalent
Accuracy	<1 mm RMS	<1 mm RMS	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.	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
Dental Drill Console	Integrated: Bien Air Motor (Model No. MOT MX-I LED 3RD GEN) (K092214) Bien Air Chiropro L System (Model No. CA 20:1 L Micro-Series) (K983183)	Standalone: Aseptico Drill Motor (Model No. AEU7000LNE-70V) (K030163) SE Analysis Anthogyr Mont Blanc handpiece (Aseptico Model No. AHP-85MBFO-CX) (K070084)	Equivalent. The subject device contains an integrated Drill console supplied by Bien Air that has been user validated, bench tested, and IEC-60601-1 tested to ensure the device is as safe and effective as the predicate. The integration of the drill motor allows for the addition of safety mitigations and controls.
Energy			
Supply Voltage	120V	120V	Equivalent
Phases	1	1	Equivalent
Type of Current	AC	AC	Equivalent
Rated Frequency (HZ)	50/60 Hz	50/60 Hz	Equivalent

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
Rated Power Input (VA)	1200 VA	600 VA	Equivalent. Although the subject device has an increased power input it is within the commercial specification for breaker control. Testing has been performed to show that the device is as safe and effective as the predicate.
Types and Ratings of external accessible fuses	10.0 A for 240 V	5.0 A for 240 V	Equivalent. The subject device has an increased external fuse rating to support an increase in power output. Testing has been performed to show that the device is as safe and effective as the predicate.
Type of Protection against Electric Shock	Class I Equipment	Class I Equipment	Equivalent
Degree of Protection against Electric Shock	Type B Drill motor Type BF Patient Tracker	Type BF	Equivalent. The subject device incorporates a Drill Console

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
			supplied by Bien Air, which has been user validated, bench tested, and IEC-60601-1 tested to show device is as safe and effective as the predicate
Equipment Suitable for use in the presence of Flammable Mixtures?	No	No	Equivalent
Mode of Operation	Continuous Operation	Continuous Operation	Equivalent
Reprocessing, Sterilization, and Shelf Life			
Reprocessing Classification	Single-use and Non-Critical reusable	Single-use and Non-Critical reusable	Equivalent
Reprocessing Method	General Cleaning, Intermediate-level disinfection, High-level disinfection, and Cleaning & Sterilization	General cleaning, High-level disinfection, and Cleaning & Sterilization	Equivalent. The subject device contains additional cleaning steps. Testing has been performed to show that the device as is safe and effective as the predicate.
Sterilization Method	Provided unsterile, end user moist heat sterilized	Provided unsterile, end user moist heat sterilized	Equivalent
Shelf life	Currently, there are no components or ancillary components of the system designed from degradable materials or materials prone to expiration	Currently, there are no components or ancillary components of the system designed from degradable materials or materials prone to expiration	Equivalent
Biocompatibility			
Patient Contact	Surface device limited duration	Surface device limited duration	Equivalent

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
Biocompatibility	Mucosal membrane, tissue, bone, dentin contact	Mucosal membrane, tissue, bone, dentin contact	Equivalent
Materials	YomiLink Bone (YLB): Body: IXEF HC-1022 NT000 (Natural 50% Glass Fiber Polyarylamide) Sleeve: Ti-6AL-4V-ELI Insert: Al 7075-T6 YomiLink Teeth (YLT): Body: IXEF HC-1022 NT000 (Natural 50% Glass Fiber Polyarylamide) Screw: Al 7075-T6 Insert: Al 7075-T6 YomiLink Arch (YLA): Body: Avaspire AV-651CF30 Epoxy: Loctite EA M-31 CL Insert: Al 7075-T6 IntraOral Fiducial Array (IOFA): Main body: Avaspire AV-651 CF30 Fiducial Beads: Silicon Nitride Epoxy: Loctite EA M-31CL epoxy Screw: Al 7075-T6	YomiLink Bone (YLB): Body: IXEF HC-1022 NT000 (Natural 50% Glass Fiber Polyarylamide) Sleeve: Ti-6AL-4V-ELI YomiLink Teeth (YLT): Body: IXEF HC-1022 NT000 (Natural 50% Glass Fiber Polyarylamide) Screw: Al 7075-T6 YomiLink Arch (YLA): Body: Avaspire AV-651CF30 Epoxy: Loctite EA M-31 CL IntraOral Fiducial Array (IOFA): Main body: Avaspire AV-651 CF30 Fiducial Beads: Silicon Nitride Epoxy: Loctite EA M-31CL epoxy Screw: Al 7075-T6	Equivalent. The addition of the insert to YLB, YLT, and YLA does not introduce new materials. The Al 7075-T6 material is being used in the predicate device YLT and IOFA products. Testing has been performed to show device is as safe and effective as the predicate. Materials were added to reduce the risk of cross-threading.
Software/Firmware & Cybersecurity			
Level of Concern	Enhanced	Major	Equivalent
Yomi Plan Software Version	v3.0	v2.6.1	Equivalent. The software has the same functionality as the predicate software with exception of Voice Controls. Software and Human Factors testing has been verified and validated

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
			to ensure the device is as safe and effective as the predicate.
Operating System	Windows 11 24H2	Windows 11 24H2	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.	Equivalent
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	• 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	Equivalent. Subject device and predicate have same functionality with exception of voice controls. The subject device has been verified and validated to ensure the device is as safe and effective as the predicate.

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
	• Allow the user to plan multiple implants • Measure distances and angles in the plan • Voice recognition and controls	• Allow the user to plan multiple implants • Measure distances and angles in the plan	
CT to STL alignment	Enables different ways to import STL files so they can be aligned to the coordinate system of the user's choice (relative to the CT or relative to the choice of another STL)	Importing STL files is limited in alignment regarding which coordinate system is used as the reference.	Equivalent
Dual Arch Workflow	Uses a single case file to capture both upper and lower arches on a single patient.	Uses two case files to plan each of the upper and lower arches for a single patient in separate files.	Equivalent. Consolidating the two arches of the same patient into a single case file makes to streamline the workflow.
Restorative Planning	Contains basic generic crown planning functionality using standard crown libraries, with additional functionality around morphing crowns and biocopy (mirroring existing crowns).	Contains basic generic crown planning functionality using standard crown libraries.	Equivalent. Enhancements for more crown planning.
Patient and robot positioning work volume guidance	Patient and robot positioning guidance includes horizontal, vertical, and angulation guidance.	Patient and robot positioning guidance includes horizontal and vertical guidance only.	Equivalent.
Baseline of force sensor	Baselining can only be performed if the arm is a certain proximity away from the patient workspace. It is automatically performed during startup and can be executed by the user with a button press.	Baseline can be performed at any arm position. It can be executed by the user with a button press.	Equivalent
YomiLink Bone (YLB) planning.	YLB planning enables a "snap" function that finds the best fit to the segmented bone in the model.	YLB planning requires the user to place it without any automatic adjustments relative to the bone.	Equivalent
Proximity threshold for distance from implant to anatomy.	Has a minimum value of 1mm as the distance threshold for generating a warning, eliminating the possibility that the user can proceed without warnings or a threshold too small to generate appropriate warnings.	Has a minimum value of 0mm as the distance threshold for generating a warning, which enables the user to effectively remove warnings.	Equivalent
Bone reduction planning	Bone reduction can account for soft tissue thickness in addition to the bone removal amount	Bone reduction only accounts for the bone removal amount	Equivalent
Implant info hover	Shows basic implant information on	Shows basic implant information on	Equivalent

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
display	hover plus the max depth that was reached	hover	
VTK Render Library	VTK library version 9	VTK library version 8	Equivalent
Surgeon Preferences	Implant brand, model, and model specifics are available as settings in surgeon preferences	Implant brand and model are available as settings in surgeon preferences	Equivalent
Case feedback	Makes available restorative feedback in the case feedback section during shutdown	No restorative feedback in the case feedback section during shutdown.	Equivalent
Implant library	Contains major implant models in the library plus several new additions	Contains major implant models in the library	Equivalent
Handpiece gestures	User interface allows for mouse / keyboard / gesture interaction to change between Free, Pause, and Guided modes. Gestures (e.g. double-tap, pull, etc.) enable transition between Free to Pause, Pause to Free, Drill to Free, and Free to Guided. All mode changes are accompanied by visual and audio confirmation cues.	User interface requires mouse / keyboard / gesture interaction to change between Free, Pause, and Guided modes. Gestures (e.g. double-tap) enable transition from Free to Pause mode. All mode changes are accompanied by visual and audio confirmation cues.	Equivalent The addition of more gestures enables the user holding the handpiece to have more direct control over the modes.
Control software response to guide arm joint limits, singularities, and potential wrist / base collisions	Control software provides warnings regarding joint limits, singularities, and potential wrist / base collisions at an improved response rate	Control software provides warnings regarding joint limits, singularities, and potential wrist / base collisions	Equivalent
Tracker arm joints	Grounding brushes in the joint interfaces. PCB reliability improvement. Generate fewer false positive errors.	Pogo pins in the joint interfaces. Occasional false positive errors from the joints.	Equivalent. Grounding brushes and PCB improvements enable greater reliability.
YomiLink Teeth (YLT)	compatible with bite blocks	Not easily compatible with bite blocks	Equivalent
Intraoral Fiducial Array (IOFA)	IOFA has small, medium, and large sizing.	IOFA only has a single size available.	Equivalent. Allows for accommodation of more patients.
Implant planning on the Osteotomy Page	Only allows depth adjustments	Allows full range of adjustments	Equivalent Restricting freedom of changes to only the most

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
			common reduces the chance of unintended plan adjustments
YomiLink Bone (YLB) Proximity Warnings	The YLB warning uses the more appropriate threshold value for determining if a warning is appropriate.	The YLB warning uses various thresholds to determine a collision risk for collisions between implant, screw, and nerve.	Equivalent
Wi-Fi	Always Active	Always Active	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 C63.27-2021 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	Equivalent. A new version of the standard IEEE ANSI C63.27:2021 has been introduced. The device has been tested to ensure it is as safe and effective as the predicate.
Interface	Windows based Graphical User Interface (GUI) and voice commands	Windows based Graphical User Interface (GUI)	Equivalent. Subject device offers the addition of voice commands that have been user validated and bench tested to ensure the device is as safe and effective as the predicate.
Cybersecurity	AAMI TIR57:2016 ANSI/AAMI SW96:2023 IEC 80001-5-1 Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions September 27, 2023	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Issued October 2, 2014	Equivalent. The subject device was designed, built, and tested to meet the latest

Technological Characteristics	Subject Device: Yomi S Robotic System	Primary Predicate: Yomi Robotic System with YomiLink Arch (K231018)	Comparison
			standards and ensure it is as safe and effective as the predicate.
Electrical Safety			
Electrical Safety	Compliance with the following: IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION ANSI/AAMI ES60601-1:2005®2012 and C1:2009/® 2012 and A2:2010/® 2012 (Consolidated Text) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. IEC 80601-2-77 Edition 1.0 2019-07 ISO15223-1:2021-07 ISO 14971:2019	Compliance with the following: IEC 606011:2005 + Corr. 1 (2006) + Corr. 2 (2007) ANSI/AAMI ES60601-1:2005®2012 and C1:2009/® 2012 and A2:2010/® 2012 (Consolidated Text) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. ISO15223-1:2012 BS EN ISO 14971:2012	Equivalent Testing for subject device was performed to latest standard with declaration of conformity to ASCA.
Electromagnetic Compatibility (EMC)	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Compliance with IEC 60601-1-2:2007	Equivalent testing for subject device was performed to latest standard with declaration of conformity to ASCA.

Performance Testing

Performance testing was conducted to verify and validate that the subject Yomi S Robotic System software application, hardware components, and accessories meet all relevant functional and system requirements. Therefore, ensuring that the system is as safe and as effective and substantially equivalent to the predicate device.

Usability Human Factors Validation testing
The Yomi S Robotic System underwent human factors software validation in accordance with the FDA's "Applying Human Factors and Usability Engineering to Medical Devices" Final Guidance, (February 2016).

Biocompatibility testing
Biocompatibility evaluation for Yomi S components was conducted in accordance with International Standard ISO-10993-1:2018, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process. The battery of testing included ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity, ISO 10993-10:2021, Biological evaluation of medical devices – Part 10: Test for skin sensitization, ISO10993-12:2021 Biological evaluation of medical devices – Part 12 Sample preparation and reference materials, and ISO 10993-23:2021 Biological evaluation of medical devices – Part 23 Test for irritation.

Cleaning/ Sterilization Verification and Validation Testing
Cleaning was conducted in compliance with Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. U.S. FDA March 2015, ANSI/AAMI ST98:2022, Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices, and AAMI TIR12:2020 (R2023): Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers

EMC Testing
EMC testing has been conducted on the Yomi S in accordance with various recognized industry standards by a recognized third-party organization. IEC 60601-1 Edition 3.2 2020 Consolidated Version, ANSI/AAMI ES60601-1:2005®2012 and C1:2009/® 2012 and A2:2010/® 2012 (Consolidated Text) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance was used for product safety, IEC 60601-1-2:2014/A1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests, EN60601-1-2:2015/A1:2021 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests, and 80601-2-77 Medical electrical equipment – Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment

Software and Cybersecurity Verification and Validation Testing
Software verification and validation (V&V) testing was performed in compliance with FDA's "Guidance for the Content of Premarket Submissions for Device Software Functions" (Jun 2023). As a failure or latent flaw in the software could directly lead to minor injury, the software was assigned an "enhanced" level of concern. Software development and testing followed a robust methodology aligning with IEC 62304 Edition 1.1:2015, the aforementioned FDA software guidance, and FDA's "General Principles of Software Validation" (January 2002). The thorough testing and analysis of results provide strong assurance of the device's intended performance.
Cybersecurity development and testing was performed in accordance with Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025) and Postmarket Management of Cybersecurity in Medical Devices (December 2016).

Based upon the information provided within this 510(k) Premarket Notification, we conclude that the Yomi S is substantially equivalent to the identified predicate device. The Subject Device has passed testing for appropriate verification, validation, and performed per its intended use. Therefore, it can be considered substantially equivalent to the Predicate Device

Conclusion

The subject of this submission is to introduce the Yomi S Robotic System, a next-generation modification of the Yomi Robotic System, intended to assist dental surgeons by providing guidance during dental implant procedures. There are no changes to the intended use compared to the predicate device. The performance testing demonstrates substantially equivalent performance of the subject device as compared to the predicate.