June 14, 2022

Neocis Inc.
William Tapia
VP RA/QA
2800 Biscayne Blvd Suite 600
Miami, Florida 33137

Re: K211466
Trade/Device Name: Yomi Robotic System with YomiPlan Go
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: May 20, 2022
Received: May 20, 2022

Dear William Tapia:

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
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)*
K211466

Device Name
Yomi Robotic System with YomiPlan Go

Indications for Use *(Describe)*
Yomi is a computerized robotic navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides robotic navigational guidance of the surgical instruments. 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

K211466

I. Submitter

Neocis Inc.

2800 Biscayne Blvd.

Suite 600

Miami, FL 33137

Tel: 1-855-9NEOCIS

Contact Person: William Tapia, VP RA/QA

Date Prepared: June 14, 2022

II. Device

Trade Name: Yomi Robotic System with YomiPlan Go

Common Name: Dental Stereotaxic Instrument

Classification Name: Bone cutting instrument and accessories (21 CFR 872.4120)

Classification: Class II

Product Code: PLV

III. Predicate Device

Neocis Guidance System (NGS) with YomiPlan v2.0 (K202264)

IV. Reference Device

Orthosoft Navitrack System-Optical TKR CT-Less System (K021760)

V. Indications for Use

Yomi is a computerized robotic navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides robotic navigational guidance of the surgical instruments. 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.

VI. Device Description

The subject of this submission is YomiPlan Go, a feature of the Yomi Robotic System which enables the use of the system without the uploading of a preoperative CT scan. The dynamic planning feature in K202264 requires a pre-operative CT scan for use. This submission includes a new workflow called YomiPlan Go and provides instructions on how to use this feature without the need of uploading a CT scan to the Yomi system. This planning involves placing the robotic arm drill tip to the point where an osteotomy is to be performed i.e., the surgeon performs

planning with their direct visualization of the anatomy and with the use of the robotic arm to select where the osteotomy is to be performed. YomiPlan Go gives surgeons the ability to perform an osteotomy under robotic guidance at the point that the surgeon selects on the patient's anatomy. The selected point, axis, and trajectory are maintained by the robotic arm while the surgeon performs the osteotomy.

Principal of Operation

YomiPlan Go gives surgeons the ability to place implants on the trajectory defined by the axis and location of the robotic arm drill tip for any selected implant, without the use of a preoperative CT scan uploaded to the Yomi System. This feature allows surgeons to place implants with precision without a preloaded CT scan. With YomiPlan Go, the surgeon selects the implant and then creates the desired path for the planned osteotomy by positioning the robotic arm drill tip at the site of where the osteotomy is to be performed.

Intended Patient Population

Based on a clinical study performed with YomiPlan Go (G210363), the intended population for YomiPlan Go was determined to be:

- Healthy adults 18 years of age or older with sufficient bone height and width appropriate for dental implant surgery
- Partially or fully edentulous patients

Preplanning with YomiPlan Go

Preplanning with YomiPlan Go is similar to that of traditional freehand technique as no CT image is actively referenced within YomiPlan. It is important to note that this does not preclude the surgeon from taking a pre-operative image and using it mentally as consideration for the freehand planning. The surgeon uses the system to indicate the plan on the patient by observing the patient's specific anatomy that is plainly visible.

The clinical study performed via G210363 demonstrated that YomiPlan Go could be used to successfully capture the trajectory of the osteotomy based mainly on the position of the drill bit tip established by the surgeon and was adequate to provide placement of the implant at the position determined by the surgeon. In the study, YomiPlan Go was able to provide guidance which used a single point with a trajectory and resulting in placement of the implant at the position established by the surgeon.

Labeling for YomiPlan Go

Labeling (i.e., instructions for use, training) is an important part of YomiPlan Go. The following are key points from these materials:

- We recommend preoperative CT as standard of care for consultation and diagnosis. No imaging is required by Yomi Go software for preoperative planning or intraoperative guidance.
- Accuracy is not a specification or an advantage of YomiPlan Go, however precision is an important specification which has been validated through performance testing.
- The surgeon must use clinical judgment in determining the best plan (position, angle, and depth) based on any anatomy that is plainly visible as well as any pre-operative X-rays or CT they may have taken of the patient.
- Use of YomiPlan Go yields less position accuracy relative to a CBCT than the guided technique for osteotomy placement in which CBCT scanning and digital intraoral impressions are used

to generate a virtual representation of the patient's jaw and oral anatomy, and the exact position of the implant is determined in advance of treatment.

Use of Anatomical Cues to Define Trajectory

The implant position and angle are defined by the surgeon by using the drill tip as a pointer. This enables the surgeon to indicate to the system the desired position and angle based on any anatomical cues they believe are relevant, e.g., neighboring teeth, bone ridge, extraction socket, etc. It is up to the surgeon to plan the implant appropriately based on the patient's clinical condition and rely on their medical training and ability to visualize the relevant anatomy of the patient.

VII. Substantial Equivalence Discussion

The table below summarizes a comparison of YomiPlan Go with the predicate NGS with Yomi Plan 2.0 (K202264).

Feature	Subject Device Yomi Robotic System with YomiPlan Go K211466	Predicate Device NGS with Yomi Plan v2.0 K202264	SE Analysis
Indications for use	Yomi is a computerized robotic navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra- operative) phases of dental implantation surgery. The system provides software to preoperatively plan dental implantation procedures and provides robotic navigational guidance of the surgical instruments. Yomi is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants. When Yomi Plan 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.	The Neocis Guidance System (NGS) 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 NGS is intended for use in partially edentulous and fully edentulous adult patients who qualify for dental implants. When Yomi Plan 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. The output of Yomi Plan is to be used with the Neocis Guidance System (NGS).	Equivalent - Updated to include reference to robotic arm.
Contraindications	Most surgical dental implant placement involves three-dimensional placement into a non-visible space. Two-dimensional radiographs may provide important information, but they often lack the oral-facial dimension that completes the picture. more-detailed information from 3D x-ray imaging is needed, most frequently, CBCT imaging. Complications in implant dentistry are common and can range from minor to severe. One of the most common complications in implant dentistry is implant malposition. This can result in a host of complications: fenestrations, dehiscences and recession, difficult restoration, poor biomechanics, loss of interproximal structure, damage to adjacent	None	Different – difference validated as acceptable with successful completion of G210363

Feature	Subject Device Yomi Robotic System with YomiPlan Go K211466	Predicate Device NGS with Yomi Plan v2.0 K202264	SE Analysis
	anatomy, and many others. Use of the YomiPlan Go is contraindicated when the intended implant location has concerns related to bone volume, architecture, and proximity to critical anatomic structures, such as nerves, maxillary sinus or nasal floor or neurovasculature.		
OS	Windows 10	Windows 10	Identical
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.	Identical
Preplanning Steps	• Preplanning is performed by the surgeon by direct visualization of the patient's anatomy and placing the drill tip at the desired location and angle. The dimension of the implant is identified in YomiPlan Go and the trajectory established by the surgeon is captured.	• The predicate device uses a preoperative CBCT scan which is uploaded to YomiPlan to support a a surgeon's planning of the desired implant placement.	Equivalent
Level of Concern	Moderate	Moderate	Identical
Installation	Windows Installer .msi file	Windows Installer .msi file	Identical
Origin	Proprietary	Proprietary	Identical
OTS Software	TeamViewer	TeamViewer	Identical
Hardware	No changes (activate/use pre-existing network features)	No changes (activate/use pre-existing network features)	Identical
Wireless data transmission over LAN	Yes, via integrated hardware, tested according to: • AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. • IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence	Yes, via integrated hardware, tested according to: • AAMI TIR69: 2017 Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. • IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence	Identical
Interface	Windows based GUI	Windows based GUI	Identical
System Accuracy / Precision Specifications	Accuracy: N/A for YomiPlan Go Precision: Upper 95% Probability with 95% Model Fit < 1.00 mm	Accuracy: Upper 95% Probability with 95% Model Fit < 1.00 mm Precision: Upper 95% Probability with 95% Model Fit < 1.00 mm	Substantially Equivalent - specifications for precision are the same. Differences determined to not significantly impact overall SE profile of YomiPlan Go as validated by successful

Feature	Subject Device Yomi Robotic System with YomiPlan Go K211466	Predicate Device NGS with Yomi Plan v2.0 K202264	SE Analysis
			completion of G210363.

To support the difference in technological characteristics of preoperative planning without the need to upload a CT image substantial equivalence of this characteristic is comparable to Orthosoft Navitrack System-Optical TKR CT-Less System (K021760):

Yomi Robotic System with YomiPlan Go VS Reference Device			
Features Related to Preplanning the	**Yomi Robotic System with YomiPlan Go**	**Orthosoft CT-Less**	**Why Differences Do Not Affect SE**
Trajectory/Implant Position			
Preoperative Imaging	None entered in the software. The surgeon may optionally take an X-ray or CT and use that mentally during the procedure.	None entered in the software. The surgeon may optionally take an X-ray or CT and use that mentally during the procedure.	SAME
Intraoperative Planning	No CT is used for guidance during surgery	No CT is used for guidance during surgery	SAME
Image Registration and Fiducial Markers	There is no image registration and there are no fiducial markers because there is no image to register to.	There is no image registration and there are no fiducial markers because there is no image to register to.	SAME
Intraoperative Data Gathering for Planning	The surgeon observes the physical location, e.g., neighboring teeth, bone (if flapped), soft tissue, etc.	Since the surgeon cannot visibly observe all the anatomical landmarks necessary for planning, they capture coordinate system elements through point digitization, e.g. hip center, knee landmarks, etc., to guide their planning. The data gathered is mapped to a generic image, but this is still very dissimilar from what the actual CT would be.	Equivalent - Neither system incorporates preoperative patient specific imaging for planning. Both rely on patient specific data either observed or captured with calculations to finalize the plan intraoperatively.

Benefit / Risk Analysis

The FDA Guidance Document entitled "*Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics*" was reviewed to prepare the following benefit/risk discussion in order to support the claim of substantial equivalence.

Primary Differences Between Predicate and Subject Device	1. Planning: Planning is based on the user's own direct visual examination of the patient's anatomy guided by the Yomi Guide Arm. Predicate device planning is based on both a patient-specific CT scan and direct visual examination. 2. Osteotomy: With YomiPlan Go, there is no CT scan to reference while performing the osteotomy. The predicate device presents the CT scan to the user which can then be used as reference during the osteotomy. All other aspects of performing the osteotomy are the same when comparing YomiPlan Go to the predicate device. 3. YomiPlan Go IDE data from G210363 showed that the average angular deviation was higher with YomiPlan Go. The study also showed that the range of angular deviations from the IDE was within the range of angular deviations from the Varga, et al study for freehand (see Varga article reference below).
Assessment of Benefits	Benefits compared to the predicate device: 1. YomiPlan Go can enable a faster workflow and greater adoption of guided surgery. 2. YomiPlan Go does not require a pre-operative CT scan therefore clinician and staff and patient exposure to x-rays is reduced. Benefits compared to freehand surgery: 1. YomiPlan Go provides a depth stop. This prevents over drilling, which can happen accidentally in freehand surgery. 2. By holding the drill steady, YomiPlan Go prevents skiving, i.e. slipping off of a knife-edge ridge of bone or slipping into an extraction socket or into soft bone. 3. It enables precision throughout repeated drill stages of multiple diameter drill bits. YomiPlan Go guides the user to the same position and angle even after switching drill bit diameters as they proceed through drilling the osteotomy. This precision is not easy to achieve with a freehand surgery technique. 4. YomiPlan Go enables parallelism. 5. YomiPlan Go provides guidance without the workflow burdens of CT image capture, registration, and pre-planning.
Assessment of Risks Related to Differences	1. Use of Yomi Active does present some risk associated with lack of use of a CT scan in the identification and protection of critical anatomical structures. Potential harms related to Yomi Active includes potential damage to the maxillary/mandibular nerves (temporary or permanent in duration depending on case). However, the risks associated with not using a CT scan uploaded to the Yomi System are considered to be similar to current freehand technique. Since freehand is considered by many to be the standard of care today in healthy patients with adequate bone, the risk is considered acceptable. 2. Critical structures are still protected with YomiPlan Go constraining the drill position and angle to match the plan set by the surgeon. It creates a depth stop and prevents skiving into unintended areas. The difference is that the plan does not use CT reference in the software, but the surgeon still has the ability to observe physically where they want the implant to be placed, and they also have the option to capture a pre-operative X-ray or CT and use it for "mental navigation" of the planning. 3. Any false sense of accuracy and appropriate position of the implant that the user may infer from the use of Yomi with CT-based guidance is mitigated with labeling e.g., instructions for use update to include appropriate warnings, marketing materials to also clearly differentiate between benefits and risks associated with using YomiPlan Go and Yomi CT-Guided, and a training program which includes materials outlining the above as well. 4. The difference in average angular deviation was found to be acceptable as evidenced by the CRF feedback from the (3) investigators after their completion of each case and by the (1) independent 3rd party clinical review of all 15 cases from the IDE i.e., feedback from the investigators that they had no vital anatomical structure concerns after completion of each procedure.

VIII. Nonclinical Performance Testing

This submission includes certain nonclinical performance testing including verification (software run-through, repeatability) and end user validation to confirm that users' needs have been satisfied while using Yomi with YomiPlan Go. End user validation was performed by a surgeon in a simulated use environment on typodonts.

IX. Clinical Testing

A clinical study (G210363) was performed in order to support substantial equivalence of YomiPlan Go to the predicate device. The primary objective of this study was to evaluate human factors related issues with YomiPlan Go during the preoperative and intraoperative use with the

Yomi Robotic System. The secondary objective focused on evaluating accuracy of the YomiPlan Go. This included a comparison of pre-operative CBCT scans on which implants are planned in ideal locations with postoperative CBCT scans capturing the actual placement of implants placed clinically with the YomiPlan Go. It also included a third-party oral surgeon's assessment regarding safety to ensure no critical structures are damaged, an evaluation for parallelism for implants that are to be placed parallel to one another, and an assessment of restorability. The information from this study was used to guide device modifications with particular focus on informing changes to the device labeling/instructions for use to ensure appropriate use of the YomiPlan Go.

The investigation was a prospective, multi-center, single-arm study, in which partially or fully edentulous patients had as part of their treatment single or multiple implant placement in the maxilla or the mandible. The subjects enrolled in the study had to satisfy certain inclusion criteria:

- Age more than 18 years at inclusion
- Signed informed consent
- Partially or fully edentulous patients that will have implant placement in the maxilla or the mandible as part of their treatment
- Must have sufficient bone height and width appropriate for dental implant surgery as evaluated on a Cone Beam Computed Tomography (CBCT) survey

A total of 44 of implants were placed in fifteen (15) patient arches with Yomi Active. Each of the (5) sites had (3) partial and (2) full arch dental restorations performed by each investigator. The study was performed by general dentists. A 3rd party oral surgeon performed an independent clinical assessment of all cases.

Each investigator provided subjective data through completion of quantitative and open-ended subjective questionnaires. There were also no serious adverse events during the conduct of this clinical study. Overall, according to the qualitative survey, the investigators determined that the YomiPlan Go met its design and performance requirements.

An adverse event did occur with one subject where the implant was transported into the sinus during hand torquing. The surgeon placed another implant to complete the dental restoration at the tooth site and completed an intervention on a later date to remove the implant. The surgeon documented on the CRF the severity of this event as "minor" and an unlikely relationship to Yomi Active. Per the surgeon, the robot was able to maintain the reference point for the osteotomy protocol that followed the initial osteotomy. After further Neocis investigation, root cause of this event was related to user error due to the surgeon hand torquing the implant deeper.

YomiPlan Go accuracy was also assessed by comparing the preoperative plans to their respective post-operative implant placement. The precision, depth and lateral error of the YomiPlan Go is equivalent to the predicate. Angular deviations were higher with YomiPlan Go than with the predicate device (see summary table below).

Comparison Metric	**Raw Data of Implant Placements Grouped by Patient, Absolute Values, reported in Mean/StdDev**		
	Depth Error (mm)	**Lateral Error (mm)**	**Angular Error (degs)**

Investigator Plan on PreOp CT vs Investigator PostOp CT of Final Implant Placement	1.38 +/- 0.71	2.04 +/- 1.59	12.91 +/- 7.56

These results were found to be within a similar range to freehand accuracy data. However, accuracy is not a specification or an advantage of YomiPlan Go, whereas precision is a specification for the system and is supported by benchtop verification testing.

X. Supporting Clinical References

The angular accuracy of the YomiPlan Go is higher than the predicate. To support the difference in performance the following articles provide support regarding performance between YomiPlan Go as compared to freehand technique:

- *Dynamic Navigation for Dental Implant Surgery, Penchal, et al, Oral Maxillofac Surg Clin North Am, Nov, 2019* – In line with this article, YomiPlan Go provides a better balance of guidance and workflow disruption. YomiPlan Go provides guidance without the workflow burdens of CT image capture, image registration, and pre-planning.
- *Digital Implant Planning and Guided Implant Surgery – Workflow and Reliability, Schubert, et al, BR Dent J, Jan 2019* – This article discussed ideal workflows and improved reliability during guided implant surgery. In line with this article, YomiPlan Go does not require a pre-operative CT scan therefore clinician and staff and patient exposure to x-rays is avoided.
- *Evaluating the Health Economic Implications and Cost-Effectiveness of Dental Implants: A Literature Review, Vogel, et al, Int J Oral Maxillofac Implants, Mar-April 2013* – This article discusses the positive economic implications of more patients having access to dental implant surgery. Since YomiPlan Go does not require a CT scan, general dentists who perform this procedure in a freehand manner, their patients, and thus in general health economics, could all benefit with YomiPlan Go.
- *Factors Influencing the Accuracy of Freehand Implant Placement: A Prospective Clinical Study, Schnutenhaus S, et al, Dent J (Basel), May, 2021* - Risks associated with YomiPlan Go can be considered similar to current freehand technique. Since freehand is considered by many to be the standard of care today in healthy patients with adequate bone, the risk associated with YomiPlan Go is considered acceptable. This article supports this conclusion. Schnutenhaus S, et al, also included a reference to a randomized clinical study by Varga E, et al (i.e., *Varga E., Jr., Antal M., Major L., Kiscsatari R., Braunitzer G., Piffko J. Guidance means accuracy: A randomized clinical trial on freehand versus guided dental implantation. Clin. Oral Implant Res. 2020*), where the deviations resulting from freehand implant placements and the various implant placements with the aid of drilling templates were compared. They found an average angular deviation of 7.03° in a freehand procedure with a range of 0.7–21.3°.
- *Image Guidance for Implants Improves Accuracy and Predictability, Compendium of CE in Dentistry, Ganeles, et al, Nov/Dec 2011* – The article discussed how surgeons have the option to capture a pre-operative X-ray or CT and use it for “mental navigation” of the planning. This is similar to how a preoperative image would be used with YomiPlan Go.

XI. Conclusion

The substantial equivalence discussion, risk profile comparisons, and testing described above demonstrate that YomiPlan Go and the predicate device have many similarities and can be

considered similar. There were some differences noted with the clinical test data such as the difference in the performance of the predicate (angular deviation of 3.3°) to the performance of the subject device (angular deviation of 12°) and performance of freehand (angular deviation range of up to 21°). These differences were found to be acceptable as evidenced by the CRF feedback from all (3) investigators after their completion of each case and by the (1) independent 3rd party clinical review of all 15 cases from the IDE i.e., feedback from the investigators was that they had no vital anatomical structure concerns after completion of each procedure. Also, when weighing the benefits (e.g., faster workflows when YomiPlan Go is indicated; less radiation exposure) against any risks associated with YomiPlan Go (e.g., less accuracy and pre-planning of critical structures, does not require the use of a preloaded CT scan onto the Yomi system for planning), it was concluded that YomiPlan Go is substantially equivalent to the predicate device.