July 28, 2021

Neocis Inc.
William Tapia
Vice President Regulatory Affairs/Quality Assurance
2800 Biscayne Blvd Suite 600
Miami, Florida 33137

Re: K211129
Trade/Device Name: Neocis Guidance System (NGS) with Intraoral Fiducial Array
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: July 1, 2021
Received: July 2, 2021

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)*
K211129

Device Name
Neocis Guidance System (NGS) with Intraoral Fiducial Array

Indications for Use *(Describe)*
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.

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 – K211129

I. Submitter

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

Contact Person: William Tapia, Vice President Regulatory Affairs/Quality Assurance
Date Prepared: July 27, 2021

II. Device

Trade Name: Neocis Guidance System (NGS) with Intraoral Fiducial Array
Common Name: Dental Stereotaxic Instrument
Classification Name: Bone cutting instrument and accessories (21 CFR 872.4120)
Classification: Class II
Product Code: PLV

III. Predicate Devices

- Primary Predicate –
  - Neocis Guidance System (NGS) (K161399)

- Reference Devices:
  - Neocis Guidance System (NGS) with Fiducial Array Splint (FAS) (K202348)
  - Neocis Guidance System (NGS) with Clamped Chairside Patient Splint (C-CPS) (K202100)

IV. Indications for Use

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.

V. Device Description

In terms of FDA regulations, the Neocis Guidance System (NGS) is a dental stereotaxic instrument (Product Code PLV) and a powered surgical device for bone cutting (21 CFR 872.4120) (Figure 1).

In terms of previously FDA-cleared indications for use (K200805), 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.

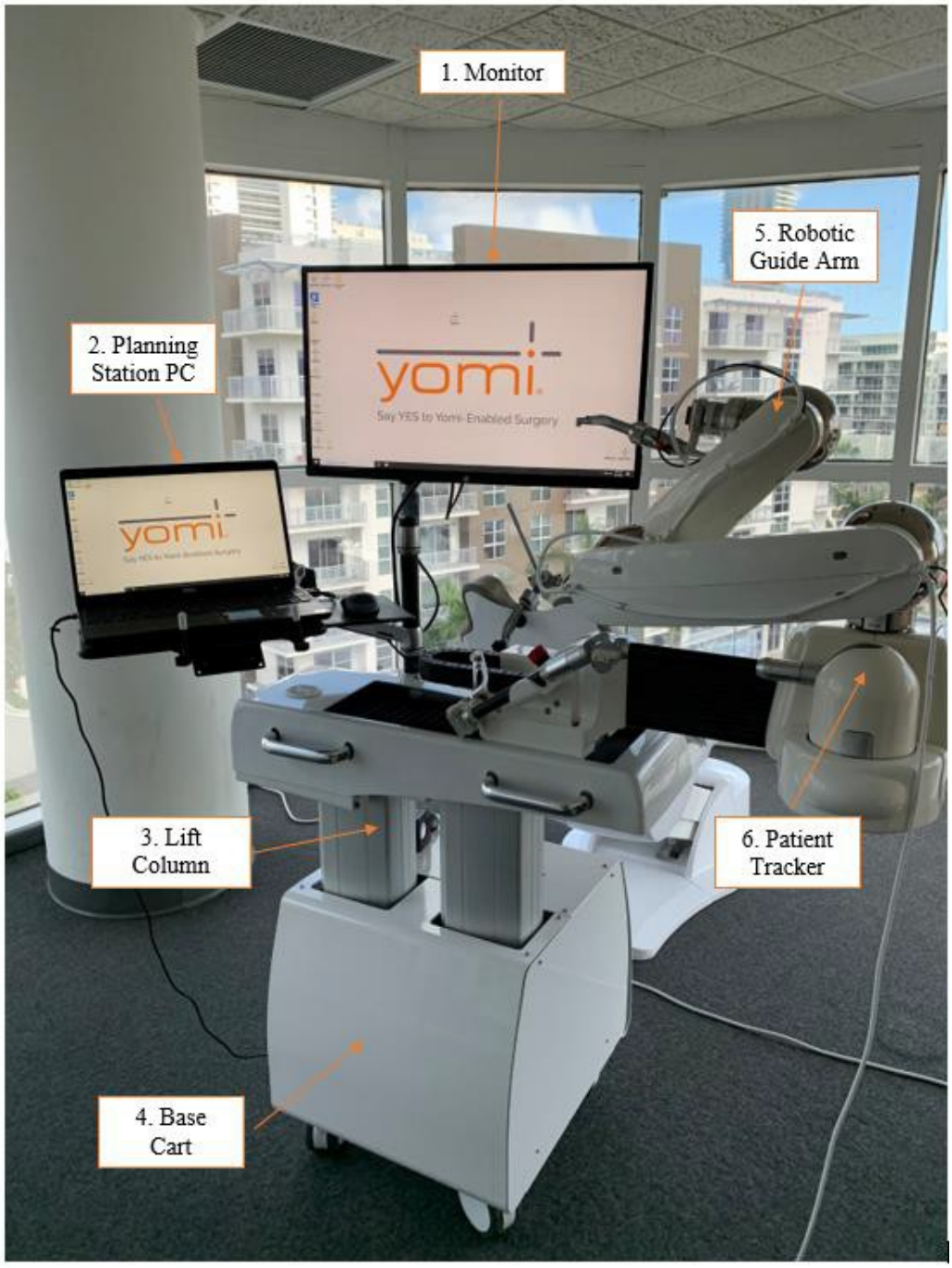

Figure 1. Overview of the Neocis Guidance System (NGS). Major components list below.

1. **Monitor:** Provides visibility of Yomi Plan for the user and operative team during a procedure. Displays the same information as the Planning station laptop PC

2. **Planning Station Laptop PC**: Used to execute Yomi Plan for planning and surgery. This PC is used during the procedure as well to execute commands for the Guide Arm. There is not separate keyboard. (Not intended for removal and use by itself for planning. Remote preplanning shall be executed on a different third party PC that is not connected to the NGS or provided by Neocis.)

3. **Lift Column:** Supports the Robotic Guide Arm and Patient Tracker assembly and is used to adjust the height of the assembly.

4. **Base Cart**: Supports the NGS, provides mobility with four swivel casters and locks in position with the foot brake lever. Contains control PC and UPS.

5. **Robotic Guide Arm:** Used to assist the surgeon in performing the surgery. Holds dental drill and provides haptic feedback on position with respect to the plan.

6. **Patient Tracker:** Attached to Patient Splint via the End Effector to monitor and relay any changes in patient position.

The system allows the user to plan the surgery virtually in Yomi Plan (K191363-cleared for use alone on third party PCs for preplanning). The operative plan is based on a cone beam computed tomography (CBCT) scan of the patient, which is used to create a 3-D model of the patient anatomy in our planning software. The plan is used by a guidance system to provide physical, visual, and audible feedback to the surgeon during the implant site preparation. The NGS robotic arm holds and guides a standard FDA-cleared third party powered bone cutting instrument (K191605).

The patient tracking portion of the NGS is comprised of linkages from the patient to the NGS, which include the Chairside Patient Splint (CPS) (K173402) or Edentulous Patient Splint (EPS) (K200805), the End Effector (EE) and the Patient Tracker (PT). The Patient Splint is attached to the contralateral side of the patient's mouth over stable teeth. The CPS is placed on the patient using on-label dental materials (K182776) prior to the presurgical CBCT scan. The EPS is placed using bone screws prior to the presurgical CBCT scan (appropriate local anesthesia is required).

A Fiducial Array (FA) with radio-opaque fiducial markers is placed on the CPS prior to the CBCT scan so the virtual plan can be related to the physical space of the system using the markers. The PT is an electromechanical feedback system that is connected to the CPS on the patient, which relays information to the NGS 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, position, and depth to accommodate the patient movement, which will maintain the accuracy of the osteotomy.

For partially edentulous patients, surgeons now have the option to use our new Clamped

Chairside Patient Splint (CCPS) (K202100). The implant process occurs in two phases: (1) The dental surgeon plans the surgical procedure with the planning software, on the day of surgery or sometime prior if a pre-operative CT scan was taken at an earlier visit. A virtual dental implant, selected from the dental implant library or using a generic model, both contained within our planning software (Yomi Plan), is placed at the desired location in the virtual patient model within our planning software. The software highlights critical anatomical structures to avoid, such as the inferior alveolar nerve or maxillary sinuses. (2) When the dental implant plan is optimized, the NGS provides precise and accurate guidance of the dental surgical instruments according to the pre-operative plan. The NGS robotic arm, which holds the powered bone cutting tool, provides haptic feedback to the surgeon by constraining the motion of the bone cutting instrument to the plan. This allows the surgeon to feel resistance to attempts at motions that may deviate from the plan. The bone cutting tool's foot pedal control is not connect to the NGS guide arm. Once the guide arm places the bone cutting tool into position according to the operative plan, the surgeon must activate the tool using the provided foot pedal associated with the bone cutting tool control box. The surgeon may modify the plan intraoperatively, if needed, has direct visualization of the patient anatomy, and is always in control of the surgical instrument.

Key safety features include:

- Emergency stop
- Automatic software-controlled safety pause triggered by joint or force limits
- Audio and visual queues
- Drill torque limits provided by the drill control console
- Full surgeon control and direct visualization of the surgical field

The subject of this submission is adding Intraoral Fiducial Array (IOFA) as a new device accessory based on a previously cleared design.

Figure 2. LLUR and LRUL Intraoral Fiducial Arrays.

The IOFA is intended for use in clinical sites with reduced scan volumes. The IOFA is designed to reside with all the fiducial beads within the patient's mouth. The IOFA can only be used with the C-CPS.

The Intraoral Fiducial Array corresponds directly to the type of C-CPS being used. There are four basic types of C-CPS.

- Lower Left/ Upper Right (LLUR) Posterior- sits on teeth 11-15 for the maxilla or teeth 27-31 for the mandible.
- Lower Right/ Upper Left (LRUL) Posterior- sits on teeth 2-6 for the maxilla or teeth 18-22 for the mandible.
- Lower Left/ Upper Right (LLUR) Anterior- sits on teeth 6-11 for the maxilla or teeth 22-27 for the mandible.
- Lower Right/Upper Left (LRUL) Anterior- sits on teeth 6-11 for the maxilla or teeth 22-27 for the mandible.

A LLUR C-CPS requires an LLUR Intraoral Fiducial Array, and an LRUL C-CPS requires an LRUL Intraoral Fiducial Array. See Figure 2 for LLUR and LRUL Fiducial Arrays.

The IOFA uses kinematic features to attach to the C-CPS and therefore has only one correct orientation.

VI. Substantial Equivalence (SE) Discussion

The indications for use (IFU) and contraindications of the subject device have remained the same as the predicate and reference devices. Acrylates allergy contraindication was removed since it is no longer applicable. Contraindications remain the same as the previously cleared reference device K202100. The subject device represents a design change to the predicate device. They are functionally equivalent.

a. Comparison of the Indications for Use and Contraindications

The indications for use (IFU) and contraindications of the subject device have remained the same as the predicate and reference devices. Acrylates allergy contraindication was removed since it is no longer applicable. Contraindications remain the same as the previously cleared reference device K202100. The subject device represents a design change to the predicate device. They are functionally equivalent.

Table 1. Comparison of the Indications for Use and Contraindications

Technological Characteristics	**K211129** **IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**Substantial Equivalence Analysis**
Indications for Use (IFU)	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 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 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 accurate navigational guidance of surgical instruments, with regard to pre-operative planning	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	No difference.

Technological Characteristics	**K21xxxx** **IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**Substantial Equivalence Analysis**
			in dental implantation procedures.	guidance of the surgical instruments.	
Contraindications	The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a Neocis Clamped Chairside Patient Splint (C-CPS) rigidly throughout a surgical procedure. The Neocis Chairside Patient Splint (C-CPS)	The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a Splint rigidly throughout a surgical procedure. Patients with allergies to methyl methacrylates.	The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a FAS rigidly throughout a surgical procedure.	The Neocis Guidance System is not intended for use with patients that have insufficient bone or teeth to retain a Neocis Clamped Chairside Patient Splint (C-CPS) rigidly throughout a surgical procedure.	Acrylates allergy contraindication not needed. Contraindications remain the same as the previously cleared reference device K202100.

Technological Characteristics	**K21xxxx** **IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**Substantial Equivalence Analysis**
	should not be affixed to patients that exhibit: • Periodontal disease to include loose teeth and inflamed tissue • Fixed orthodontic appliances, bridges, or dental implants • Patients with a history of jaw or TMJ pain		The FAS should not be affixed to patients that exhibit: • Periodontal disease to include loose teeth and inflamed tissue • Fixed orthodontic appliances, bridges, and/or dental implants • Patients with a history of jaw or TMJ pain • Patients with allergies to methyl methacrylates	The Neocis Clamped Chairside Patient Splint (C-CPS) should not be affixed to patients that exhibit: • Periodontal disease to include loose teeth and inflamed tissue • Fixed orthodontic appliances, bridges, or dental implants • Patients with a history of jaw or TMJ pain	

b. Comparison of Technology to Predicate Devices

There are no changes to the non-splint NGS hardware or software in this submission.

c. Head-to-Head Comparison

VII. Table 2. Head-to-Head Comparison

Technological Characteristics	NGS with IOFA *Subject Device*	K161399 *Predicate*	K200348 FAS *Reference Device*	K202100 C-CPS *Reference Device*	SE Analysis
Patient Contacting Materials	Ixef®-HC-1022 Avaspire AV-651 CF30	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
NGS Power Supply	120VAC/60 Hz	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
Type of Protection against Electric Shock	Class I Equipment	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
Equipment Suitable for use in the presence of Flammable Mixtures?	No	Same as the subject device	Same as the subject device.	Same as the subject device.	Same

Technological Characteristics	**NGS with IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**SE Analysis**
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Same as the subject device	Same as the subject device.	Same as the subject device.	Same

Technological Characteristics	**NGS with IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**SE Analysis**
Electromagnetic Disturbances	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
Ingress Protection	IPX0	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
Mode of Operation	Continuous Operation	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
System Lateral Accuracy	RMS < 1 mm	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
System Depth Accuracy	RMS < 1 mm	Same as the subject device	Same as the subject device.	Same as the subject device.	Same

Technological Characteristics	NGS with IOFA *Subject Device*	K161399 *Predicate*	K200348 FAS *Reference Device*	K202100 C-CPS *Reference Device*	SE Analysis
System Angular Accuracy	RMS < 6.0°	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
CT Scan Quality Requirements	0.3 mm Voxel, 0.3 mm Slice Thickness, Matrix 512 x 512, Full 13 cm 21 sec, Multi 2 DICOM format.	Same as the subject device	Same as the subject device.	Same as the subject device.	Same
F/T Sensor Force Measurement Range	+/- 30 N	Same as the subject device	Same as the subject device	Same as the subject device	Same
F/T Sensor Torque Measurement Ra nge	+/- 2 Nm	Same as the subject device	Same as the subject device	Same as the subject device	Same
F/T Sensor Single Axis Force Overload Limit	200 N	Same as the subject device	Same as the subject device	Same as the subject device	Same
F/T Sensor Single Axis Torque Overload Limit	20 Nm	Same as the subject device	Same as the subject device	Same as the subject device	Same

Technological Characteristics	NGS with IOFA *Subject Device*	K161399 *Predicate*	K200348 FAS *Reference Device*	K202100 C-CPS *Reference Device*	SE Analysis
Upper limit specification for Guidance Arm Translation Speed	1.25 m/s	Same as the subject device	Same as the subject device	Same as the subject device	Same
Storage Requirements	Store powered at Room Temperature (68°F to 76°F or 20°C to 24.4°C) and standard ambient humidity (5% to 95%) in a dust free, clean environment.	Same as the subject device	Same as the subject device	Same as the subject device	Same
Patient Tracking	Patient Tracking Arm	Same as the subject device with CPS	Same as the subject device	Same as the subject device	Same
Affixation of tracking technology to patient	Clamped Patient Splint	Same as the subject device with CPS	Same as the subject device with FAS	Same as the subject device	Same
Patient attachment removal	Standard dental techniques	Same as the subject device.	Same as the subject device.	Same as the subject device.	Same

Technological Characteristics	**NGS with IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**SE Analysis**
Fiducials	The Fiducial Array attaches to the splint during the CT scan to provide a reference in the image.	The Fiducial Array attaches to the splint during the CT scan to provide a reference in the image.	Not required	The Fiducial Array attaches to the splint during the CT scan to provide a reference in the image.	Same
Kinematic mount	KM integrated into splint.	The Kinematic Mount attaches to the splint to provide a mounting point for the Fiducial Array and Patient Tracker.	KM integrated into the FAS	KM integrated into splint.	Same
Biocompatibility	Yes (ISO 10993-1, -5, -10, -12)	Yes (ISO 10993-1, -5, -10, -12)	Same as the subject device	Same as the subject device	Same
Sterilization	Steam (ISO 17665-1)	Steam (ISO 17665-1)	Same as the subject device	Same as the subject device	Same
Planning Software	Neocis Planning Software Application v2.0 (K202264)	Same as the Subject Device	Same as the Subject Device	Same as the Subject Device	Yomi Plan v2.0 cleared under K202264. SE under K161399

Technological Characteristics	**NGS with IOFA** ***Subject Device***	**K161399** ***Predicate***	**K200348** **FAS** ***Reference Device***	**K202100** **C-CPS** ***Reference Device***	**SE Analysis**
Software Level of Concern	Moderate	Same as the Subject Device	Same as the Subject Device	Same as the Subject Device	Same

The design changes in this submission involve adding a new Intraoral Fiducial Array (IOFA), which is a modified version of the Fiducial Array. The IOFA is a separate part that mounts to the Clamped Chairside Patient Splint (C-CPS) and contains fiducial markers for registration in CBCT scans prior to surgery. The IOFA is intended to sit intra-orally, which allows for use smaller field of view CT scanners. We have implemented the same affixation methods and technology as the predicate device. We have adopted the same indications for use as the predicate device.

We think that the subject device:

- Has a legally marketed predicate,
- Has the same intended use as the predicate,
- Has somewhat different technological characteristics that do not raise different questions of safety and effectiveness,
- For which we have provided adequate performance testing to show that
- Those different technological characteristics are substantially equivalent to the predicate device.

Therefore, the subject device is substantially equivalent.

VIII. Performance Testing

Use of FDA-Recognized Consensus Standards

A risk analysis, sterilization validation, and biocompatibility testing were conducted on the final finished device per the following standards:

- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Applications of risk management to medical devices
- ANSI AAMI ISO 17665-1:2006/(R)2013 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices
- ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ANSI AAMI ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ANSI AAMI ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- Center for Devices and Radiological Health (CDRH) (2015). Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff (FDA Amended June 9, 2017)

Verification

- Registration Testing
- Autoclave Cycle Testing
- Kinematic Mount Repeatability
- Scan Artifact Testing
- Fit Clearance Simulation
- Total System Accuracy
- IOFA Deflection Test

Validation

- IOFA End User Validation
  - To validate the user requirements of the Intraoral Fiducial Array, as performed by a surgeon (end user). This validation activity is a nonclinical surrogate that simulates the process of applying, qualitatively evaluating rigidity, and removing a Intraoral Fiducial Array directly to a patient.

Animal or clinical testing was not conducted for the subject device.

Conclusion:

The IOFA is substantially equivalent to the predicate. There are no changes to the intended use or to the fundamental technology, and there are no new risks to patients or users.