January 4, 2023

Image Instruments GmbH
% Greg Holland
Sr. Partner
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, California 92606

Re: K213263
Trade/Device Name: OnyxCeph³™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, PNN
Dated: November 30, 2022
Received: December 5, 2022

Dear Greg Holland:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE.
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)*
K213263

Device Name
OnyxCeph³™

Indications for Use *(Describe)*
OnyxCeph³™ software is intended to be used for the medical purpose of managing and evaluating two-dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only. The use of OnyxCeph³™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

The software can be used to digitally perform certain image-based orthodontic workflows, such as metric and angular evaluation of image data.

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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5. 510(k) Summary - K213263

510(k) Owner	Image Instruments GmbH Niederwaldstr. 3 09123 Chemnitz Germany Phone: +49 371 9093140 Facsimile: +49 371 9093149
Contact person	Greg Holland Regulatory Specialists, Inc. 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949.262.0411 Fax: 949.552.2821 Email: greg@regulatoryspecialists.com
Submission Date	January 3, 2023
Common Name	Orthodontic Software
Trade Name	OnyxCeph³™
Classification Name	Radiological Image Processing System
Regulation	892.2050
Class	Class II
Panel	Dental
Primary Product Code	LLZ
Secondary Product Code	PNN
Primary Predicate Device	K053010 VISTADENT™ AT COMPLETE From: Dentsply INTL., Inc.
Reference Device	K171634 Ortho System™ From: 3Shape A/S K192475 NemoFAB From: Software Nemotec S.L.

Description

OnyxCeph³™ dental aligner software device is designed for the simulation and planning of orthodontic and maxillofacial surgical combination treatments, based on virtual models and CT / DVT volume data. OnyxCeph³™ is a software device that includes both 3D and 2D versions both suitable for dental facilities to use for orthodontic treatments.

Intended Use

OnyxCeph³™ is a software only device and is intended to be used for the medical purpose of managing and evaluating two-dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only who have received dedicated training for use of the software. Diagnostic and therapeutic decisions cannot be motivated exclusively or even mainly on evaluation results provided by the software.

Indications for Use

OnyxCeph³™ software is intended to be used for the medical purpose of managing and evaluating two-dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only. The use of OnyxCeph³™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

The software can be used to digitally perform certain image-based orthodontic workflows, such as metric and angular evaluation of image data.

Technological Characteristics

The predicates and the Image Instruments GmbH OnyxCeph³™ were compared in the following areas and found to have similar technological characteristics and to be equivalent. Both predicates are shown as a comparison in separate tables.

	OnyxCeph³™ K213263 Subject Device	VISTADENT™ AT COMPLETE K053010 Predicate Device
Intended Use	Orthodontic Software	Orthodontic Software

	OnyxCeph³™ K213263 Subject Device	VISTADENT™ AT COMPLETE K053010 Predicate Device
Indications for Use	OnyxCeph³™ software is intended to be used for the medical purpose of managing and evaluating two-dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only. The use of OnyxCeph³™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software. The software can be used to digitally perform certain image- based orthodontic workflows, such as metric and angular evaluation of image data.	VISTADENT™ AT COMPLETE software is a digital database for storing, retrieving and printing images that also has the ability to perform image manipulation and cephalometric analysis.
Product Code	LLZ	LLZ
2 Dimensional Image Import	Yes	Yes
2 Dimensional Image Adjust	Yes	Yes

	OnyxCeph³™ K213263 Subject Device	VISTADENT™ AT COMPLETE K053010 Predicate Device
2 Dimensional Cephalometric Evaluation	Yes	Yes
2 Dimensional Image Combination	Yes	Yes
2 Dimensional Image Comparison	Yes	Yes
2 Dimensional Mirroring	Yes	Yes
CO/CR-Conversion	Yes	Yes
Ricketts VTO	Yes	Yes
2 Dimensional Treatment Simulation	Yes	Yes
Windows Based	Yes	Yes
Activation by Key	Yes	Yes
Client Requirements	Hardware Type, CPU, RAM, Disk, Network, Graphic Board, Desktop Resolution	Hardware Type CPU, RAM, Disk, Network, Graphic Board, Desktop Resolution
Client Requirements	Not Required	Internet Access, Internet Speed
Server Requirements	Hardware Type, CPU, RAM, Disk, Network, Port Sharing	Hardware Type, CPU, RAM, Disk, Network, Port Sharing

	OnyxCeph³™ K213263 Subject Device	Ortho System 3Shape A/S K171634 Reference Device
Intended Use	Orthodontic Software	Orthodontic Software
Indications	OnyxCeph³™ software is intended to be used for the medical purpose of managing and evaluating two- dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only. The use of OnyxCeph³™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software. The software can be used to digitally perform certain image- based orthodontic workflows, such as metric and angular evaluation of image data.	The 3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.
Product Code	LLZ	PNN

	OnyxCeph³™ K213263 Subject Device	Ortho System 3Shape A/S K171634 Reference Device
2 Dimensional Evaluation	Yes	Yes
2 Dimensional Cephalometric Evaluation	Yes	No
3 Dimensional Evaluation	Yes	Yes
Supported anatomical areas	Maxilla and Mandible	Maxilla and Mandible
Determine arch shape	Yes	Yes
Determine wire length	Yes	Yes
Determine tooth width	Yes	Yes
Determine Bolton	Yes	Yes
Determine space analysis	Yes	Yes
Determine overbite	Yes	Yes
Determine occlusion	Yes	Yes
Extract/Segment Volume Scans	Yes	Yes
Combine Bony and Dental Scan Data	Yes	Yes
Windows Based	Yes	Yes
Data Storage	Local	Local / Cloud
Activation by Dongle	No	Yes

	OnyxCeph³™ K213263 Subject Device	Ortho System 3Shape A/S K171634 Reference Device
Activation by Key	Yes	No
Client Requirements	Hardware Type, CPU, RAM, Disk, Network, Graphic Board, Desktop Resolution	Hardware Type CPU, RAM, Disk, Network, Graphic Board, Desktop Resolution
Client Requirements	Not required	Internet Access, Internet Speed
Server Requirements	Hardware Type, CPU, RAM, Disk, Network, Port Sharing	Hardware Type, CPU, RAM, Disk, Network, Port Sharing

Although the Indications for Use Statement for the subject device is different from the predicate device, K053010, the intended use of the software is the same, to allow for two-dimensional and three-dimensional evaluation of images. The predicate device includes Internet Access which is not required for the subject device. The subject device includes 3-dimensional evaluation capabilities; whereas the predicate device does not. However, the reference devices support this function.

The reference device, K171634, was included to support the 3-dimensional evaluation capabilities of the subject device. This reference device does not include 2-Dimensional Cephalometric function, and activation by Key. However, the 2-Dimensional Cephalometric function is supported by the predicate device. The reference device offers activation by Dongle. In addition, the reference device supports the use of Data Storage via the Cloud and requires Internet Access whereas the subject device does not.

Additional reference device, K192475 was included to support the devices intended use for supporting the treatment planning process of orthognathic procedures.

In summary, the similarities between the subject device, OnyxCeph³™, and the predicate devices are functionally very similar. The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

Nonclinical Testing

Software Validation conducted per FDA Guidance for Software Contained in Medical Devices
IEC 62304 – Software Life Cycle Processes

Clinical Testing

Clinical testing has not been included and is not required to demonstrate substantial equivalence.

Conclusion

Based on the similarities between the intended use, indications, principle of operation, features and technical data, the subject device, OnyxCeph³™, is found to be substantially equivalent to the predicate device.