April 29, 2022

Oryx Dental Software INC
℅ Ms. Mary Vater
Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Road
SHREWSBURY VT 05738

Re: K220684
   Trade/Device Name: Oryx Cloud Imaging
   Regulation Number: 21 CFR 892.2050
   Regulation Name: Medical image management and processing system
   Regulatory Class: Class II
   Product Code: LLZ
   Dated: March 7, 2022
   Received: March 8, 2022

Dear Ms. Vater:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
   and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K220684

Device Name
Oryx Cloud Imaging

Indications for Use *(Describe)*
Oryx Cloud Imaging is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in a form of digital images. The system uses a Web-based interface and includes acquisition, editing and storage of digital images. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices, or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.

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.

510(k) SUMMARY
K220684

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I.   SUBMITTER

Oryx Dental Software INC
1001 Fairview Avenue North
Seattle, WA 98109
Tel: 202-758-4111

Contact Person: Meritxell Martinez
Date Prepared: March 25th, 2022

II.   DEVICE

Device Trade Name:	Oryx Cloud Imaging
Device 510(k):	K220684
Classification Name:	Medical Image Management and Processing System
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Device Panel:	Radiology
Product Classification Code:	LLZ

III.   PREDICATE DEVICE

Predicate Manufacturer:	Curve Dental, Inc.
Predicate Trade Name:	Curve Image 2.0
Predicate 510(k):	K112974
Classification Name:	Medical Image Management and Processing System
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Device Panel:	Radiology
Product Classification Code:	LLZ

No reference devices were used in this submission.

IV.   DEVICE DESCRIPTION

Oryx Cloud Imaging is a cloud-based dental imaging software that allows access to diagnostic images on any Mac or PC with an active internet connection.
Oryx Cloud Imaging is feature rich, including full feature parity with traditional client-server based dental imaging software.

Oryx Cloud Imaging is a Class II dental imaging software that includes the ability to acquire, view, annotate, and organize dental radiographs and color images. Oryx Cloud Imaging integrates with most major client-server and web-based practice management software. Images stored using Oryx Cloud Imaging are saved using lossless compression, and can be exported as DICOM, PNG, JPEG, or PDF files. Oryx Cloud Imaging is a software-only dental image device which allows the user to acquire images using standard dental imaging devices, such as intraoral X-ray sensors, intraoral cameras, and scanners. Oryx Cloud Imaging is imaging software designed for use in dentistry. The main Oryx Cloud Imaging software functionality includes image acquisition, organization, and annotation. Oryx Cloud Imaging is used by dental professionals for the visualization of patient images retrieved from a dental imaging device or scanner, for assisting in case diagnosis, review, and treatment planning. Dentists and other qualified individuals can display and review images, apply annotations, and manipulate images. Oryx Cloud Imaging is a standalone product but is designed to work cooperatively with dental practice management software that is used for scheduling, clinical note taking, and billing. The software operates upon standard PC hardware and displays images on the PC's connected display/monitor. The subject device is the Oryx PACS software; the computer or the monitor are not part of the submission.

Oryx Cloud Imaging neither contacts the patient nor controls any life sustaining devices. Diagnosis is not performed by this software but by doctors and other qualified individuals. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

Oryx Cloud Imaging is intended for use on adult and pediatric patients.

Oryx Cloud Imaging Software has a Moderate Level of Concern.

V.   INDICATIONS FOR USE

Oryx Cloud Imaging is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in a form of digital images. The system uses a Web-based interface and includes acquisition, editing and storage of digital images. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices, or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.

VI.   COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

	Oryx Cloud Imaging	Curve Image 2.0 – K112974	Substantial Equivalence Comparison
Product Code	LLZ	LLZ	Same.
Regulation	21 C.F.R. 892.2050	21 C.F.R. 892.2050	Same.
Class	II	II	Same.
Intended Use	Oryx Cloud Imaging is an internet- based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in a form of digital images. The system uses a Web- based interface and includes acquisition, editing and storage of digital images. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices, or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.	CURVE IMAGE is an internet- based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in a form of digital images. The system uses a Web- based interface and includes acquisition, editing and storage of digital images. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices, or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.	Same.
Indications for Use	Oryx Cloud Imaging is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in a form of digital images. The system uses a Web- based interface and includes acquisition,	CURVE IMAGE is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in a form of digital images. The system uses a Web- based interface and includes acquisition,	Same.

	editing and storage of digital images. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices, or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.	editing and storage of digital images. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices, or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.	
Environment of Use	Dental offices.	Dental offices.	Same.
Performance Characteristics & Principle of Operation	**Basic Technology:** Web-based, software application **Features:** ● Browsing Images by Date and/or Source ● Viewing an Image ● Uploading and Image file Acquiring an Image from Web camera ● Acquiring an Image from a TWAIN Device ● Acquiring an image from standard dental imaging devices ● Copying an Image to the Local Computer ● Saving a Modified Image ● Annotating an Image ● Zooming In on an Image ● Cropping an Image ● Inverting Colors on an Image ● Rotating an Image (increments of 90 degrees)	**Basic Technology:** Web-based, software application **Features:** ● Browsing Images by Date and/or Source ● Viewing an Image ● Uploading an Image File ● Acquiring an Image from a Web Camera ● Acquiring an Image from a TWAIN Device ● Acquiring image from standard dental imaging devices ● Copying an Image to the Local Computer ● Saving a Modified Image ● Annotating an Image ● Zooming In on an Image ● Cropping an Image ● Inverting Colors of an Image	Same.

	- Flipping an Image Horizontally or Vertically - Increasing/Decreasing Image Brightness - Increasing/Decreasing Image Contrast - Adjusting Gamma Function - Lossless Image Compression - Zoom depth: absolute 1x, Fit and Relative	- Rotating an Image (increments of 90 degrees) - Flipping an Image Horizontally or Vertically - Increasing/Decreasing Image Brightness - Increasing/Decreasing Image Contrast - Adjusting Gamma Function - Lossless image compression - Zoom dept: absolute 1x, Fit and relative	
Technical Characteristics	- Web-based application and interface - Secure data transmission (HTTPS) - Database Management and Storage - Secure server and Infrastructure	- Web-based application and interface - Secure data transmission (HTTPS) - Database Management and Storage - Secure server and Infrastructure	Same.
Administration	- User login - Account management - Security administration privileges for Administrator, Basic User, Clinical User and Practice Management User	- User login - Account management - Security administration privileges for Administrator, Basic User, Clinical User and Practice Management User	
Patient Management	Patient profile and data management	Patient profile and data management	Same.
Scheduling	Appointment managements functions with calendar	Appointment managements functions with calendar	Same.
Billing	Setting up billing and insurance information	Setting up billing and insurance information	Same.
Insurance Management	Retrieve Insurance payments	Retrieve Insurance payments	Same.
Claims Management	Create and manage Insurance claims	Create and manage Insurance claims	Same.
Dental Charting	Dental Chart layout and treatment plans management	Dental Chart layout and treatment plans management	Same.

Perio Charting	● Perio Chart, perio exam and perio graph management	● Perio Chart, perio exam and perio graph management	Same.
Patient notes and History	● Patient text notes, note history	● Patient text notes, note history	Same.
Prescriptions	● Prescription notepad writer	● Prescription notepad writer	Same.
Patient Education	● Patient education reports, documents, video links and interface	● Patient education movies and interface	Same.
Summary of Non-Clinical Testing	● Product Risk Assessment ● Software Modules Verification Tests ● Software Validation Test	● Product Risk Assessment ● Software Modules Verification Tests ● Software Validation Test	Same.
Differences Between Two Softwares	Features: • Spyglass Tool • Two-Factor Authentication • Calibration to auto-correct orientation UI Differences: • Minor differences in UI in terms of terminology. Eg: Uses "Templates" as opposed to "Mounts", Imaging acquisition and viewing are on two seperate windows.	Features: • N/A UI Differences: • Minor differences in UI in terms of terminology and flow. Eg: Uses "Mounts" as opposed to "Templates", Imaging acquisition and viewing are from the same window.	Differences highlighted are mostly minor between the two softwares in the form of negligible UI and flow differences and features that improve on the user's experience that are available on Oryx Cloud Imaging, but not on the predicate software. None of the mentioned differences in features and UI changes any of the safety, effectiveness, or indications for use of Oryx Cloud Imaging as compared to the Curve Image predicate.

VII.   SUMMARY OF NON-CLINICAL TESTING

Oryx Dental Software INC, has conducted extensive non-clinical and validation testing of the Oryx Cloud Imaging, as a PACS system that is capable of providing reliable post-processing and display of images for dental applications. All of the different components of the Oryx Cloud Imaging software have been tested to ensure that the system as a whole provides all the capabilities necessary to operate in a manner substantially equivalent to the predicate device.

The tests performed included:
- Software Risk Assessment
- Software verification and validation testing
- Clinical Expert Evaluation

VIII. CONCLUSIONS

Based on the comparison of intended use, indications for use and technological characteristics, the Oryx Cloud Imaging software is substantially equivalent to the predicate device.