



Sota Precision Optics, Inc. dba SOTA Imaging
% Mr. W. Edward Johansen
Official Correspondent
1073 North Batavia Street, Suite B
ORANGE CA 90404

May 4, 2021

Re: K210682

Trade/Device Name: SOTA 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 9, 2021
Received: March 10, 2021

Dear Mr. Johansen:

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,

For

Thalia T. Mills, Ph.D.
Director
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)
K210682

Device Name

SOTA Cloud Imaging

Indications for Use (Describe)

SOTA Cloud Imaging is indicated for use as a clinical software application that receives images and data from Clio or Clio Prime sensors and various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, SOTA Cloud Imaging enables the storage of clinical notes and clinical exam data.

SOTA Cloud Imaging is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware. SOTA Cloud Imaging is also intended for use for diagnostic and non-diagnostic purposes in the field of Dentistry by dental professionals who are responsible for providing dental care.

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

K210682

Dated: April 30, 2021

A. Submitter's Name: Sota Precision Optics, Inc. dba SOTA Imaging

Address: 1073 North Batavia Street, Suite B, Orange, California 92867

Telephone: (714) 532-6100

Official Correspondent: W. Edward Johansen,

Telephone: (310) 795-7425

E-mail address: wedjohansen@msn.com

Address: 1239 Stanford Street, #205, Santa Monica, California 90404

B. Identification of New Device

Owner/Operator/Manufacturer: SOTA Imaging

Establishment Registration Number: 3000190675

510(k) Premarket Notification Number: K210682

Trade Name: SOTA Cloud Imaging

Common Name: Dental imaging software

Classification Name: Medical Image Management and Processing System

Product Code: LLZ

Classification: Class II

Panel: Radiology

Class: II

Panel: Radiology

Regulation Number: 21 C.F.R. §892.2050

C. Identification of Predicate Device

Owner/Operator/Manufacturer: Apertyx, Inc.

510(k) Premarket Notification Number: K132342

Trade Name: XV Web

Common Name: Dental imaging software

Classification Name: Medical Image Management and Processing System

Product Code: LLZ

Classification: Class II

Panel: Radiology

Regulation: Number: 21 C.F.R. §892.2050

D. Device Description

SOTA Cloud Imaging is a cloud-based dental imaging software that allows access to diagnostic images on any PC with an active internet connection. SOTA Cloud Imaging's single page application design makes the in-browser imaging experience fast, familiar, and simple to operate. SOTA Cloud Imaging is feature rich, including full feature parity with traditional client-server based dental imaging software. With SOTA Cloud Imaging, you can use digital dental imaging devices in a manner consistent with your existing imaging solutions, and bridge patient information either from your existing client-server-based practice management software or modern cloud-based practice management software.

SOTA Cloud Imaging is a Class II dental imaging software that includes the ability to acquire, view, annotate, and organize dental radiographs and color images. SOTA Cloud Imaging integrates with most major client-server and web-based practice management software. Images stored using SOTA Cloud Imaging are saved using lossless compression, and can be exported as DICOM, PNG, JPEG, or PDF files.

SOTA 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 and intraoral cameras.

SOTA Cloud Imaging is imaging software designed for use in dentistry. The main SOTA Cloud Imaging software functionality includes image acquisition, organization, and annotation. SOTA Cloud Imaging is used by

dental professional for the visualization of patient images retrieved from a dental imaging device or scanner, for assisting in case diagnosis, review, and treatment planning. Doctors, dental clinicians, and other qualified individuals can display and review images, apply annotations, and manipulate images.

SOTA 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.

SOTA 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.

E. Intended Use

SOTA Cloud Imaging software is designed for use by dental practices for tracing and presenting patient images which are utilized by dental professionals to assist in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed dental practitioners.

SOTA Cloud Imaging is indicated for use as a clinical software application that receives images and data from Clio or Clio Prime x-ray sensors and various other imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, SOTA Cloud Imaging enables the storage of clinical notes and clinical exam data.

It is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

SOTA Cloud Imaging interacts with imaging devices connected to a Windows PC. SOTA Cloud Imaging controls the direct capture of digital x-ray images from Clio and Clio Prime intraoral x-ray sensors and other FDA

approved radiographic imaging devices, views and captures live image from intraoral cameras via USB 2.0 or video capture card, imports images from various sources such as radiographic devices, flatbed scanners, digital cameras, and generic image devices, exports, e-mail, prints images, processes digital images with several tools to enhance their diagnostic value, and creates a database of patients and store images in patient folders on cloud server storage.

F. Indications for Use

SOTA Cloud Imaging is indicated for use as a clinical software application that receives images and data from Clio or Clio Prime sensors and various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, SOTA Cloud Imaging enables the storage of clinical notes and clinical exam data.

SOTA Cloud Imaging is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware. SOTA Cloud Imaging is also intended for use for diagnostic and non-diagnostic purposes in the field of Dentistry by dental professionals who are responsible for providing dental care.

G. Technical Characteristics

SOTA Cloud Imaging is a software only device that is operated by users via a modern web-browser. On the server side, SOTA Cloud Imaging is written in C# and runs in a stateless containerized environment. SOTA Cloud Imaging uses Microsoft Azure SQL databases and Microsoft Azure Blob storage to store application metadata and images. On the client-side, SOTA Cloud Imaging executes in a modern web-browser using HTML5, CSS3, and JavaScript.

H. Off-the-Shelf Software

SOTA Imaging has conducted an appropriate hazard analysis and basic documentation of all off-the-shelf software prior to its utilization in the SOTA Cloud Imaging product, in accordance with the OTS Software Decision Schematic in the FDA guidance document entitled “Off-The-Shelf Software Use in medical Devices” issued on September 27th, 2019. All included off-the-shelf software is used strictly in non-diagnostic capacity and is not directly interacted with by the user. The off-the-shelf software used in this product is documented in the Software Information section of this filing.

I. Summary of Non-Clinical (bench) Performance Testing

SOTA Imaging has conducted extensive non-clinical (bench) performance testing and validation and verification testing of SOTA Cloud Imaging. All the different components of the SOTA Cloud Imaging have been stress tested to ensure that the SOTA Cloud Imaging provides all the capabilities necessary to operate in a manner substantially equivalent to the XV Web predicate.

J. Summary of Clinical Performance Testing

SOTA Imaging has performed performance testing to compare SOTA Cloud Imaging to the XV Web predicate. Based on the performance testing of the XV Web predicate and SOTA Cloud Imaging, SOTA Cloud Imaging is substantially equivalent in performance specification to the XV Web predicate. Test information can be located within the Software Documentation included with this submission.

Additionally, the results of the performance testing, which included positive and negative testing against the device requirements, predicate testing and human factors testing, has demonstrated that SOTA Cloud Imaging is safe and effective for its intended use and that SOTA Cloud Imaging is substantially equivalent to the currently marketed XV Web predicate.

K. Non-Applicable Requirements

SOTA Cloud Imaging is a software product. Therefore, the requirement of Sterilization does not apply.

SOTA Cloud Imaging is a software product. Therefore, the requirement of specifying Shelf Life does not apply.

SOTA Cloud Imaging does not contain patient contacting elements. Therefore, the requirement for Biocompatibility does not apply.

SOTA Cloud Imaging is a software product which does not have electronic components. Therefore, the requirement of Electromagnetic Compatibility does not apply.

SOTA Cloud Imaging is a software product which does not have electronic components. Therefore, the requirement of Electrical Safety does not apply.

L. Summary of Animal Performance Testing

Based on the device hazard analysis and classification SOTA Imaging has not performed animal performance testing to compare SOTA Cloud Imaging to the XV Web predicate.

M. Comparing SOTA Cloud Imaging to the XV Web predicate

The following comparison table compares SOTA Cloud Imaging to the XV Web predicate with respect to intended use, indications of use, environment of use, limitations of use, technical performance and technological characteristics and provides additional information regarding the basis for the determination of substantial equivalence.

N. SOTA Cloud Imaging and the XV Web Predicate Differences

Unlike the XV Web predicate device, SOTA Cloud Imaging does not require the installation of a separate image acquisition user interface, outside of the cloud-based web application.

None of the above-mentioned differences in features changes any of the Safety or Effectiveness or Indications for Use of SOTA Cloud Imaging as compared to the XV Web predicate.

O. Substantial Equivalence Rationale

SOTA Imaging has conducted extensive performance testing for validation and verification of SOTA Cloud Imaging and has done analysis to compare SOTA Cloud Imaging to the XV Web predicate. Based on this testing analysis SOTA Cloud Imaging provides all the capabilities necessary to operate in a manner substantially equivalent to the XV Web predicate. The comparison table compares SOTA Cloud Imaging to the XV Web predicate with respect to intended use, indications of use, environment of use, limitations of use, technical performance, and technological characteristics. The comparison chart provides additional information regarding the basis for the determination of substantial equivalence. Additionally, the results of the performance testing demonstrate that SOTA Cloud Imaging is safe and effective for its intended use. Based on the intended use, product design, performance and software information provided in this notification, SOTA Cloud Imaging is considered substantially equivalent to the currently marketed XV Web predicate.

Comparison table

510(k) Number	K132342	K210682
Device Name	XV Web	SOTA Cloud Imaging
Classification Name	Picture Archiving and Communications System (PACS)	Medical Image Management and Processing System
Common\Usual name	Dental Imaging Software	Dental Imaging Software
Manufacturer	Apteryx, Inc.	SOTA Precision Optics, Inc. dba SOTA Imaging
Classification	Class II	Class II
Regulation Number	892.2050	892.2050
Product Code	LLZ	LLZ
Classification panel	Radiology	Radiology
Medical Specialty	Dentistry	Dentistry
Implementation	Dental Office	Dental Office
Host Platform	Web Based Software Application	Web Based Software Application
Intended Use	XV Web is a Picture Archiving and Communications System (PACS) that enables dental facilities to query and access digitally stored hard and soft tissue intraoral /extraoral radiological images using an internet/web browser. A web-based interface provides users the needed functionality to display patient images and studies in commercially available web browsers. Patient images/studies can be accessed by users	SOTA Cloud Imaging is indicated for use as a clinical software application that receives images and data from Clio or Clio Prime x-ray sensors and various other imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, SOTA Cloud Imaging enables the storage of clinical notes and clinical exam data. It is intended to acquire, display,

	<p>locally within the system or across a wide-area network at distributed locations. Acquisition can be included via integration with a DICOM-compatible imaging application or server configured to forward images to the XV Web database. The system allows users to: manipulate (e.g., rotate, flip, etc.): enhance (e.g., increase or decrease brightness/contrast, gamma correction); add labels (e.g., measurements, lines, arrows, etc.), annotations to patient images/studies and other relevant operations for diagnostic purposes. XV Web is designed for medium-to-large dental practices and is intended for trained dental professionals and technicians to access, manipulate, and enhance dental images for diagnostic purposes only.</p>	<p>process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware. SOTA Cloud Imaging controls the direct capture of digital x-ray images from Clio and Clio Prime intraoral x-ray sensors and other FDA approved radiographic imaging devices, views and captures live image from intraoral cameras via USB 2.0 or video capture card, imports images from various sources such as radiographic devices, flatbed scanners, digital cameras, and generic image devices, exports, e-mail, prints images, processes digital images with several tools to enhance their diagnostic value, and creates a database of patients and store images in patient folders on cloud server storage.</p>
<p>Indications for Use</p>	<p>XV Web is a Picture Archiving and Communications</p>	<p>SOTA Cloud Imaging is indicated for use as a clinical software</p>

	<p>System (PACS) that enables dental facilities to query and access digitally stored hard and soft tissue intraoral/extraoral radiological images using an internet/web browser. A web-based interface provides users the needed functionality to display patient images and studies in commercially available web browsers. Patient images/studies can be accessed by users locally within the system or across a wide-area network at distributed locations. Acquisition can be included via integration with a DICOM - compatible Imaging and/or PACS system configured to forward images to the XV Web database. XV Web is compatible with programs that run on standard "off-the-shelf personal computers, business computers, and servers running standard operating systems. The system allows users to: manipulate (e.g.,</p>	<p>application that receives images and data from Clio or Clio Prime sensors and various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, SOTA Cloud Imaging enables the storage of clinical notes and clinical exam data.</p> <p>SOTA Cloud Imaging is intended to acquire, display, process, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute images using standard PC hardware. SOTA Cloud Imaging is also intended for use for diagnostic and non-diagnostic purposes in the field of Dentistry by dental professionals who are responsible for providing dental care.</p>
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	<p>rotate, flip, etc.); enhance (e.g., increase or decrease brightness/contrast, gamma correction); add labels (e.g., measurements, lines, arrows, etc.), annotations to patient images/studies and other relevant operations for diagnostic purposes. XV Web is designed for medium to large dental practices and is intended for trained dental professionals and technicians to access, manipulate, and enhance dental images for diagnostic purposes only.</p>	
<p>Features</p>	<p>Browsing images by date and/or source Viewing an Image Uploading an Image file (via integration with DICOM-compatible imaging application or PACS) Acquiring an Image from a Web camera (via integration with DICOM-compatible imaging application) Acquiring an Image from a TWAIN device (via integration with</p>	<p>Browsing images by date and/or source Viewing an Image Uploading an Image file Acquiring an Image from a Web cam Acquiring an Image from a TWAIN device</p>

	<p>DICOM-compatible imaging application) Acquiring an image from standard dental imaging devices (via integration with DICOM-compatible imaging application) Copying an Image to the local computer Add labels and annotations on patient images (Text, lines, arrows, ect.) Saving a Modified Image Saving an Image that has been modified with labels/overlays. Annotating an Image Zooming in on an Image Inverting Colors on an Image Rotating an Image (increments of 90 degrees) Flipping an Image Horizontally or Vertically Image contrast Increase and decrease image contrast Increase and decrease image brightness, Adjust gamma function N/A N/A</p>	<p>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 Inverting Colors on an Image Rotating an image (increments of 90 degrees) Flipping an image Horizontally or Vertically N/A Increase and decrease contrast Increase and decrease brightness Adjust gamma function Spotlight sharpness enhancement tool Staff audit logging</p>
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	N/A/ Cropping image Inverting colors of an image	Staff software-use analytics N/A N/A
Technical Characteristics	Web-based application and interface Secure data transmission (HTTPS) Database Management and Storage Secure server and Infrastructure	Responsive single page web-based application and interface Secure data transmission (HTTPS, TLS v1.2) Secure Database Management and Storage Secure server and Infrastructure Multi-zone redundant, highly available
	DICOM Compliant	DICOM File Compliant
	Lossless Image Compression	Lossless Image Compression
	Zoom Depth, fit and relative	
	XV Web is designed for medium to large dental practices and is intended for trained dental professionals and technicians to access, manipulate and enhance dental images for diagnostic and non-diagnostic purposes.	SOTA Cloud Imaging is designed for single dental practice, group dental practice, and corporate dental service organization environments. SOTA Cloud Imaging is intended for trained dental professionals and technicians to access, manipulate, and enhance dental images for diagnostic and non-diagnostic purposes.

P. Recognized Standards and Not Recognized Standard

SOTA Cloud Imaging is software that conforms to the following recognized standards.

13-79 ISO 14971: Medical Devices—Application of Risk Management to Medical Devices

5-125 IEC 62304: Medical Device Software—Software Life Cycle Processes

NR ISO 13485:2016 Medical devices --Quality management systems --Requirements for regulatory purposes

Q. Conclusion

Based on the comparison of intended use, indications for use and technological characteristics, SOTA Cloud Imaging is substantially equivalent to the XV Web predicate. SOTA Imaging has conducted extensive performance testing for validation and verification indicating that SOTA Cloud Imaging provides reliable post-processing information to ensure that SOTA Cloud Imaging provides all the capabilities necessary to operate in a manner substantially equivalent to the XV Web predicate.