K132342

DEC 2 0 2013

F.   510(k) Summary

I.   Applicant Information

Submitter Information:	Apteryx, Inc. 313 S. High St., Suite 200 Akron, OH 44308
Contact:	Kevin Crucs, President
Telephone Number:	(330) 376-0889
Date Prepared:	February 27, 2013

II.   Device Name and Classification

Proprietary Name:	XVWeb
Classification Name:	Picture Archiving and Communications System (PACS)
Classification:	Class II
Regulation Number:	892.2050
Product Code:	LLZ
Classification Panel:	Radiology Devices

III.   Predicate Devices

XVWeb is substantially equivalent to the following FDA-approved predicate devices. It is substantially equivalent with regard to indications for use, performance, and technological characteristics.

510(K) Number:	K112974
Trade Name:	Curve Image 2.0
Manufacturer:	Curve Dental, Inc.
Classification Name:	Picture Archiving and Communications System (PACS)
Classification:	Class II
Regulation Number:	892.2050
Product Code:	LLZ
Classification Panel:	Radiology Devices

510(K) Number:	K083018
Trade Name:	Centricity PACS Web Diagnostic (Web DX) PACS System
Manufacturer:	GE Healthcare Dynamic Imaging Solutions
Classification Name:	Picture Archiving and Communications System (PACS)
Classification:	Class II
Regulation Number:	892.2050
Product Code:	LLZ
Classification Panel:	Radiology Devices

IV. Device Description

XVWeb is a web-based dental picture archiving and communications system that provides a dental facility the ability to access their patient radiological image library over the internet. It is designed for deployment in medium to large dental facilities with multiple viewing stations and/or across remote sites using standard TCP/IP network infrastructures. The system uses a web-based interface that allows users to display patient images and studies in commercially available web browsers such as Internet Explorer, Mozilla, Firefox, or Google Chrome.

XVWeb includes features for dental practices to: manipulate, enhance, add labels, annotations to patient images/studies, and other relevant operations for diagnostic purposes. XVWeb includes image acquisition capabilities via integration with DICOM-compatible imaging systems that facilitate the production of original images. All images available for viewing in XVWeb have been received from DICOM compliant modalities or systems.

V. Intended Use

XVWeb 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 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 XVWeb 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.

XVWeb 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.

VI. Summary of Device Characteristics

- Query and view patient images/studies
- View single images (e.g. intraoral, panoramic and cephalometric)
- View full mouth series
- Manipulate images (e.g. Rotate increments of 90°, flip horizontal/vertically, and zoom in or out)
- Enhance images (e.g. Increase/decrease brightness, contrast and gamma correction)
- Calibrate and Add Measurement labels to Images
- Add labels and annotations on patient images (e.g. Text, lines, arrows, etc.)
- View image information
- Export a copy of an image
- Integration with a DICOM-compatible imaging application.
- Comparison of images

Table F.1 below offers a comparison of XVWeb with the aforementioned predicate devices with respect to intended use, environment of use, technical performance and operations characteristics, etc. The intent is to provide more details to demonstrate substantial equivalence with the predicate devices.

XVWeb	Curve Image (K112974)	Centricity PACS Web Diagnostic (Web DX) PACS (K0803018)
Product Code		
I.I.Z.	I.I.Z.	I.I.Z.
Regulation Number		
892.2050	892.2050	892.2050
Class		
Class II	Class II	Class II
Intended Use		
XVWeb is a Picture Archiving and Communications System (PACS) that enables dental facilities to query and access digitally stored intraoral and 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 such as Internet Explorer, Mozilla, Firefox, or Google Chrome. Patient images/studies can be accessed by any user locally within the system or across a wide-area network at distributed locations. 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. Acquisition can be included via integration with a DICOM-compatible Imaging application configured to forward images to the	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.	Centricity PACS Web Diagnostic (Web DX) PACS System by GE Healthcare Dynamic Imaging Solutions is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distrusted locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only interpreted using an FDA Approved monitor that offers at least 5 MPixels resolution and meets other technical specifications reviewed and accepted by FDA.

XVWeb database. XVWeb 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.		

Environment of Use		
Dental Offices	Dental Offices	Dental Offices and other Modalities

Performance Characteristics & Principles of Operation

Basic Technology:

Web-based software application	Web-based software application	Web-based software application

Features:

Browsing images by Date and/or Source	Browsing images by Date and/or Source	Browsing images by Date and/or Source
Viewing an Image	Viewing an Image	Viewing an Image
Uploading an image file (via integration with a DICOM-compatible imaging application or PACS).	Uploading an Image File	Uploading an Image File
Acquiring an Image from a Web Camera (via integration with a DICOM-compatible imaging application.	Acquiring an Image from a Web Camera	Acquiring an Image from a Web Camera
Acquiring an Image from a TWAIN device (via integration with a DICOM-compatible imaging application).	Acquiring an Image from a TWAIN Device	Acquiring an Image from a TWAIN Device
Acquiring an Image from a TWAIN device (via integration with a DICOM-compatible imaging application).	Acquiring image from standard dental imaging devices	NA
Copy an image to the Local Computer	Copying an Image to the Local Computer	Copying an Image to the Local Computer
Add labels and annotations on patient images (Text, lines, arrows, etc.)	Annotating an image	NA
Saving an image that has been modified with labels/overlays.	Saving a modified image	Saving a modified image
Annotating an Image	Annotating an Image	Annotating an Image
Zooming In on an Image	Zooming In on an Image	Zooming In on an Image
NA	Cropping an Image	NA
NA	Inverting colors of an image	Inverting colors of an image
Rotating an Image (increments of 90°)	Rotating an Image (increments of 90°)	Rotating an Image (increments of 90°)
Flipping an image horizontally or vertically	Flipping an image horizontally or vertically	Flipping an image horizontally or vertically
Increasing/decreasing image brightness	Increasing/decreasing image brightness	Increasing/decreasing image brightness
Image contrast	Image contrast	Image contrast

Adjusting Gamma function	Adjusting Gamma function	Adjusting Gamma function
Image measurements	Image measurements	Image measurements
DICOM Compliance	NA	DICOM compliance
NA	NA	3D Image view
Lossless image compression	Lossless image compression	JPEG and wavelet lossy image compression
Zoom depth: Fit and relative.	Zoom depth: absolute x, fit, and relative	Zoom depth: absolute 1x, 2x, 4x, 8x and relative.
Technical Characteristics		
Web-based application and interface	Web-based application and interface	Web-based application and interface
Secure data transmission (HTTPS)	Secure data transmission (HTTPS)	Secure data transmission (HTTPS)
Database Management and storage	Database Management and storage	Database Management and storage
Secure Server infrastructure	Secure Server infrastructure	Secure Server infrastructure
Administration		
User Login	User login	User login
Account Management	Account Management	Account Management
Security administration privileges for Administrator and user.	Security administration privileges for Administrator, basic user, clinical user, and practice management user	Security administration privileges for administrator, basic user, and clinical user.
Patient Management		
NA	Expanded feature: Patient profile and data management	Patient profile and data management
Scheduling		
NA	Expanded feature: Appointment management functions with calendar	NA
Billing		
NA	Expanded feature: Setting up billing and insurance information	NA
Insurance Management		
NA	Expanded feature : Retrieve insurance payments	NA
Claims Management		
NA	Expanded feature: Create and manage insurance claims	NA
Dental Charting		
NA	Expanded feature: Dental Chart layout and treatment plans management	Dental Chart layout and treatment plans management
Perio Charting		
NA	Expanded feature: Perio Chart, perio exam, and Perio graph management	NA
Patient Notes and History		
NA	Expanded feature: Patient text notes, note history	Keynotes on patient data

Prescriptions		
NA	Expanded feature: Prescription notepad writer	NA
Patient Education		
NA	Expanded feature: Patient education movies interface	NA

Table F.1

VII. Comparison Summary

The differences between the subject and the predicate devices, the reason they do not alter the indications for use, or impact the safe and effective use of XVWeb are listed below:

- Cropping an Image - Does not raise new types of Safety and Effectiveness questions. Although this feature may improve image presentation and data size, it does not improve image quality or increase diagnosis accuracy.
- Inverting colors of an image - Does not raise new types of Safety and Effectiveness questions. In regards to safety, the feature does not improve the quality of an image, therefore, does not contribute to a reduced number of retakes for a patient. Effectiveness of XVWeb is not impacted by the exclusion of the feature. Color inversion does not significantly reduce diagnostic accuracy. Diagnostic accuracy is dependant on the quality of the raw, source data.
- Patient profile and data management - An expanded feature not defined as an intended use in the predicate device(s).
- Appointment management functions with calendar - An expanded feature not defined as an intended use in the predicate device(s).
- Setting up billing and insurance information - An expanded feature not defined as an intended use in the predicate device(s).
- Retrieve insurance payments - An expanded feature not defined as an intended use in the predicate device(s).
- Create and manage insurance claims - An expanded feature not defined as an intended use in the predicate device(s).
- Dental Chart layout and treatment plans management - An expanded feature not defined as an intended use in the predicate device(s).
- Perio Chart, perio exam, and Perio graph management - An expanded feature not defined as an intended use in the predicate device(s).
- Patient text notes, note history - An expanded feature not defined as an intended use in the predicate device(s).
- Prescription notepad writer - An expanded feature not defined as an intended use in the predicate device(s).
- Patient education movies interface - An expanded feature not defined as an intended use in the predicate device(s).

VIII. Summary of Non-Clinical Testing

Apteryx has performed thorough non-clinical testing to ensure the safety and effectiveness of XVWeb. Stress testing in a simulated environment has been performed to ensure that the XVWeb system can consistently operate in a manner similar to the indications for use of the predicate devices listed. Quality assurance test activities included:

- Device Hazard Analysis
- Module Testing
- System Verification and Validation Testing

IX. Summary of Clinical Testing

Clinical trials have been performed side-by-side with current systems to ensure proper performance of the software.

X. Conclusions

The subject (XVWeb) is substantially equivalent to the predicated devices (Curve Image 2.0 and Centricity PACS Web Diagnostic [Web DX] PACS System) when comparing the intended use and technological characteristics to these predicate devices. XVWeb combines the basic features, functionality, and web-based technology of Curve Image (the stand-alone product) and Centricity PACS. The differences between the subject and the predicate devices do not alter the indications for use or raise new issues that impact the safe and effective use of XVWeb.

December 20, 2013

Apteryx, Inc.
℅ Mr. Kevin Crucs
President
313 South Hight Street, Suite 200
AKRON OH 44308

Re: K132342
    Trade/Device Name: XVWeb
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: II
    Product Code: LLZ
    Dated: October 31, 2013
    Received: November 4, 2013

Dear Mr. Crucs:

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. 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.
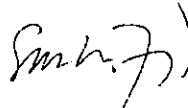
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801). please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
 and Radiological Health
Center for Devices and Radiological Health

Enclosure

F. Indications for Use Form

510(k) Number: K132342

Device Name: XVWeb

Indications for Use:

XVWeb 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 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 XVWeb database. XVWeb 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. 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.

XVWeb 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.

<table>
<tr><td align="center">**Prescription Use: Yes**
(Part 21 CFR 801 Subpart D)</td><td align="center">AND/OR</td><td align="center">**Over the Counter Use: No**
(21 CFR PART 801 Subpart C)</td></tr>
</table>

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510K_____K132342_____