



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

RealCloud Imaging Inc.  
% Mark Job  
1394 25TH STREET, NW  
BUFFALO MN 55313

July 7, 2015

Re: K151438  
Trade/Device Name: Dentrix Ascend Imaging  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: June 26, 2015  
Received: June 29, 2015

Dear Mr. Job:

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 Industry and Consumer Education 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” (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151438

Device Name

Dentrix Ascend Imaging

Indications for Use (Describe)

Dentrix Ascend Imaging is a web-based Dental Picture Archiving and Communications Systems (PACS), i.e. dental imaging software, that enables dental care facilities to acquire, process, edit, and enhance dental images.

Dentrix Ascend Imaging provides a web-based interface for image acquisition and management of images which are used in the field of Dentistry and when operated by dental professionals who are responsible for providing dental care.

Images can be acquired from dental image acquisition devices and/or consumer imaging devices such as color digital cameras. Previously acquired images or volumes can be selected for upload directly from the user's computer.

Supported images include intraoral and extraoral dental x-rays/volumes and intraoral and extraoral color images produced by intraoral video or consumer digital cameras.

Dentrix Ascend Imaging is used for diagnostic purposes in the field of dentistry. Dentrix Ascend Imaging is not intended for diagnostic use on a mobile display.

Images can be edited/enhanced (e.g. zoomed, contrast adjusted, inverted, annotated, rotated, filtered, etc...) as well as exported to standard image file formats.

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

510(k) Number: K151438

### I. Applicant Information:

Corporate Name: RealCloud Imaging Inc.

Corporate Address: 2060 Alameda Padre Serra, Suite 100

Santa Barbara, California 93013

Date Prepared: June 30, 2015

Submitter: W. Edward Johansen, Official Correspondent

Telephone Number: (310) 795-7425

E-mail address: wedjohansen@msn.com

### II. Device Name and Classification

Proprietary Name: Dentrax Ascend Imaging

Classification Name: Picture Archiving and Communications System

Common/Usual Name: Dental Imaging Software (PACS)

Classification: II

Regulation Number: 21 C.F.R. 892.2050

Product Code: LLZ

Classification Panel: Radiology

### III. Predicate Device

Dentrax Ascend Imaging is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number: K112974

Trade Name: Curve Image

Manufacturer: Curve Dental, Inc.

Classification Name: Picture Archiving and Communications System

Common/Usual Name: Dental Imaging Software (PACS)

Classification: Class II

Regulation Number: 21 C.F.R. 892.2050

Product Code: LLZ

The following table compares Dentrix Ascend Imaging to the predicate device Curve Image with respect to intended use, indications for use environment of use, limitations of use, technical performance and technological characteristics and provides more detailed information regarding the basis for the determination of substantial equivalence.

<b>510(k) Number</b>	<b>K112974</b>	<b>K151438</b>
Trade Name	Curve Image	Dentrix Ascend Imaging
Manufacturer	Curve Dental, Inc	RealCloud Imaging Inc.
Classification Name	Picture Archiving and Communication System	Picture Archiving and Communication System
Common/Usual Name	Dental Imaging Software	Dental Imaging Software
Classification	Class II	Class II
Regulation Number	21 C.F.R. 892.2050	21 C.F.R. 892.2050
Product Code	LLZ	LLZ
Classification Panel	Radiology	Radiology
Implementation	Dental Offices	Dental Offices
Host Platform	Web-based Software Application	Web-based Software Application

Indications for Use

Curve Image is an internet-based, image management software (PACS) that enables dental offices to keep hard and soft tissue charts in a form of digital images.

Curve 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.

Dentrix Ascend Imaging is a web-based Dental Picture Archiving and Communications Systems (PACS), i.e. dental imaging software, that enables dental care facilities to acquire, process, edit, and enhance dental images.

Dentrix Ascend Imaging provides a web-based interface for image acquisition and management of images which are used in the field of Dentistry and when operated by dental professionals who are responsible for providing dental care.

Images can be acquired from dental image acquisition devices and/or consumer imaging devices such as color digital cameras. Previously acquired images or volumes can be selected for upload directly from the user's computer.

Supported images include intraoral and extraoral dental x-rays/volumes and intraoral and extraoral color images produced by intraoral video or consumer digital cameras.

Dentrix Ascend Imaging is used for diagnostic purposes in the field of dentistry. Dentrix Ascend Imaging is not intended for diagnostic use on a mobile display.

Images can be edited/enhanced (e.g. zoomed, contrast adjusted, inverted, annotated, rotated, filtered, etc...) as well as exported to standard image file

<p>Features and Technical Characteristics</p>	<p>Browsing Images by Date and/or Source  Viewing an Image  Uploading and Image file  Acquiring an Image from a 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  Inverting Colors on an Image  Rotating an Image (increments of 90 degrees)  Flipping an Image Horizontally or Vertically  Increasing/Decreasing Brightness  Increasing/Decreasing Contrast  Adjusting Gamma Function  Lossless Image Compression  Zoom depth: absolute 1x, Fit and Relative  Crop Image  NA  NA</p>	<p>Browsing Images by Date and/or Source  Viewing an Image  Uploading and Image file  Acquiring an Image from a 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  Inverting Colors on an Image  Rotating an Image (increments of 90 degrees)  Flipping an Image Horizontally or Vertically  Increasing/Decreasing Brightness  Increasing/Decreasing Contrast  Adjusting Gamma Function  Lossless Image Compression  Zoom depth: absolute 1x, Fit and Relative  NA  Spotlight Image  Density Measurement</p>
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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
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The indications of use, features and technical characteristics of Dentrix Ascend Imaging and Curve Image are virtually identical.

Based on the comparison of use, indications of use, and technological characteristics Dentrix Ascend Imaging (K151438) is substantially equivalent to Curve Image (K112974) manufactured by Curve Dental, Inc. Dentrix Ascend Imaging includes the web-based technology and substantially all of the features and functionality of Curve Image. Dentrix Ascend is substantially equivalent to the predicate Curve Image.

### **Device Description**

Dentrix Ascend Imaging is web-based dental image software that provides Internet access to an image library for each patient in a practice. It also provides tools for dental practices to manipulate patient images and both acquire and upload new images in industry standard formats. Images can be annotated and tagged and are available for use. Dentrix Ascend Imaging can be accessed by the user via an internet connection and does not require traditional software installation on the user's computer.

Dentrix Ascend Imaging operates from within the Google brand ChromeWeb Browser version 39.x and higher on supported Windows and Mac Operating Systems and from within the Apple brand Safari Web Browser 8.x on Apple IOS iPad devices. Dentrix Ascend Imaging requires a minimum 17" monitor for viewing images upon a Windows or MAC PC, and operates upon an iPad device with minimum 1024 X768 resolution. The iPad device can be used for non-diagnostic purposes only.



## **Technical Overview**

Dentrix Ascend Imaging is a web based imaging program. On the server side Ascend Imaging is written in the C# language and runs on the Microsoft Windows Server 2012 R2 operating system. Ascend Imaging uses SQL to store and retrieve data from a Microsoft SQL Server 2014 database. Ascend Imaging is hosted on a Microsoft IIS server. The Ascend Imaging server technology is hosted entirely on virtual machine image. On the client side Ascend Imaging is hosted in a compatible HTML5 web browser and is written in HTML5, CSS3, and Java Script.

## **Off-the-Shelf Software**

Dentrix Ascend Imaging does not distribute or contain any Off-the-Shelf software. An OTS operating system such as Windows or Mac OSX is commonly used in conjunction with an OTS web browser such as Google Chrome to interface the user, hardware platform and the Dentrix Ascend Imaging software. Off-the-Shelf software represents no threat of direct harm to the patient. The risk of indirect harm from lack of diagnostic information relating to off-the-shelf software-malfunction is small since the operator can use traditional methods to investigate and diagnose the patient. The OTS Software in this medical device thus represents a Minor Level of Concern and should satisfy basic documentation.

## **Level of Concern**

RealCloud Imaging Inc. has determined that the level of concern for the Dentrix Ascend Imaging software is Moderate according to the analysis in Section 23, subsection A of this 510(k) submission.

## **Intended Use**

Dentrix Ascend Imaging is a web-based Picture Archiving and Communications Systems (PACS), dental imaging software, that enables dental care facilities to acquire, process, edit, and enhance dental images. Dentrix Ascend Imaging provides a web-based interface for image acquisition and management of images which are used in the field of Dentistry when used by dental professionals who are responsible for providing dental care.

Supported image types include intraoral and extraoral dental x-rays, intraoral and extraoral color images, and three dimensional volumes of dental anatomy. Images can be acquired from dental image acquisition devices and/or consumer imaging devices such as color digital cameras. Previously acquired images or volume scan be selected for upload directly from the user's computer. Images can be edited/enhanced (e.g. zoomed, contrast adjusted, inverted, annotated, rotated, filtered,

etc...) as well as exported to standard image file formats.

### **Summary of the Technical Characteristics:**

Dentrix Ascend Imaging provides the following high-level features:

- Browsing Images by Date and/or Source
- Viewing an Image
- Uploading an Image File
- Acquiring Image from a Web Camera
- Acquiring an Image from a TWAIN Device
- Acquiring image from Dental Imaging Device
- Exporting an Image to the Local Computer/other location
- Saving a Modified Image
- Annotating an Image
- Zooming In on an Image
- Inverting colors of an Image
- Rotating an Image (increments of 90 degrees)
- Flipping an Image Horizontally or Vertically
- Increasing/Decreasing Image Brightness
- Increasing/Decreasing Image Contrast

The main technical characteristics of the software are:

- Web-based Application and Interface
- Secure Data Transmission (HTTPS)
- Database Management and Storage
- Secure Server Infrastructure

### **Summary of Non-Clinical Performance Testing**

A series of non-clinical performance tests were performed. The results of the non-clinical performance testing, which included positive and negative testing against the device requirements and human factors, demonstrated that Dentrix Ascend Imaging is safe and effective for its intended use and its indications of use.

This device conforms to the following recognized standards. A Standards Data Report is included below for each standard.

- ISO 14971:2007 Medical Devices- Application of Risk Management to Medical Devices
- IEC 62304:2012 Medical Device Software - Software Life Cycle Processes

Based on the intended use, product design, performance and software information provided in this notification, the subject device is considered to be substantially equivalent to the currently marketed predicate device.

Non-clinical performance testing (bench testing) has been performed on this software product. Test information can be located within the Software section of this submission.

RealCloud Imaging Inc. has conducted extensive non-clinical performance testing and validation and verification testing of Dentrix Ascend Imaging as a Picture Archiving and Communications System (PACS) that is capable of providing reliable post-processing and display of images for dental applications. All of the different components of the Ascend Imaging have been stress tested to ensure that Dentrix Ascend Imaging as a whole provides all the capabilities necessary to operate in a manner substantially equivalent to the predicate device.

### **Non-Applicable Requirements**

No animal performance testing has been included in this submission. Based on the device hazard analysis and classification of the device animal performance testing was neither required nor performed.

No clinical performance testing has been included in this submission.

Based on the device hazard analysis and classification of the device clinical performance testing was neither required nor performed.

Dentrix Ascend Imaging is a software product. Therefore, the requirement for Sterilization does not apply.

Dentrix Ascend Imaging is a software product. Therefore, the requirement for specifying Shelf Life does not apply. Dentrix Ascend Imaging contain patient contacting materials. Therefore, the requirement for Biocompatibility does not apply.

Dentrix Ascend Imaging is a software product which does not contain any electronic components. Therefore, the requirement for Electromagnetic Compatibility and Electrical Safety does not apply.

## **Conclusions**

Based on the comparison of intended use, indications for use, and technological characteristics Dentrix Ascend Imaging (K151438) is substantially equivalent to Curve Image (K112974) manufactured by Curve Dental, Inc. Dentrix Ascend Imaging includes the web-based technology and substantially all of the features and functionality of Curve Image. Dentrix Ascend Imaging is substantially equivalent to the predicate Curve Image.