DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

U.S. Army Dental Command (DENCOM)
% Mr. Carl Alletto
Consultant
OTech, Inc.
8317 Belew Drive
MCKINNEY TX 75071

August 19, 2015

Re: K151371
Trade/Device Name: Corporate Dental Imaging (CDI) Application™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2015
Received: August 4, 2015

Dear Mr. Alletto:

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,

For

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151371

Device Name Corporate Dental Imaging (CDI) Application™

Indications for Use *(Describe)*

Corporate Dental Imaging (CDI) Application™ is a software device for general dental diagnostic imaging. It controls capture, display, transfer, enhancement, and storage of X-ray dental images from digital imaging systems.

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

May 5, 2015

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. William K. Porter
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	Corporate Dental Imaging (CDI) Application™
Common Name:	Picture, archive and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

The Corporate Dental Imaging (CDI) Application™ system is substantially equivalent to:

Device Classification Name	system, image processing, radiological
510(k) Number	K102684
Device Name	XELIS DENTAL
Original Applicant	INFINITT CO., LTD. 12f Daerung Post Tower III 182-4 Guro-Dong, Guro-Gu Seoul, KR 152-050
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	09/17/2010
Decision Date	10/01/2010
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology

Device Description: 21 CFR 807 92(a)(4)

The Corporate Dental Imaging (CDI) Application™ is a software application used for storing and displaying medical dental images. The application conforms to the DICOM 3.x standard to allow interoperability with other DICOM compliant systems. The implementation of CDI interface has been tested to assure compliance with the DICOM Conformance Statement. However, the DICOM Conformance Statement for the Subject device and the DICOM standard itself does not guarantee interoperability of the system to other vendor products. The user must compare the relevant Conformance Statements and if a successful interconnection should be possible, the user is responsible to specify an appropriate test

suite and to validate the required interoperability. A network environment may need additional functions out of the scope of DICOM.

Note: The subject device does not include any automated or semi-automated processes for the detection of nodules or other shapes.

The Corporate Dental Imaging (CDI) Application™ system is being designed as a replacement for the legacy PACS system known as DEVAA. CDI will replace the legacy PACS technologies found in DEVAA with a more robust software and hardware solution. In addition, CDI will add additional capabilities not available in legacy capture/view tools. Additional benefits include providing a global view of images through DICOM image data query across multiple service image archives and the capability to migrate existing DICOM images to new image servers. In addition, CDI offers the capability to query and retrieve images at any location within the digital enterprise for primary, ghosted and retake images.

CDI is comprised of one (1) desktop client for Modality Image Capture, one (1) web-based client for Image Viewing and Diagnostics with Microsoft SQL Server back-end database(s) for storing DICOM images. There is at least one instance of this environment. Each Military clinical post will most likely have multiple instances of this environment depending upon the volume of productivity. CDI will form the core of the acquisition and viewing operations within the enterprise architecture. CDI will capture images directly from intra-oral and extra-oral acquisition modalities, full color images from intra-oral cameras, digital cameras and other video sources. CDI is loaded onto the Acquisition PCs in the clinic where either the images will be acquired or where the images will need to be viewed. If the PC is being used to acquire images, CDI is configured to use the attached acquisition modalities. CDI is has been designed to be able to acquire an image regardless of the acquisition modality used to capture the image. CDI will use the hardware vendor's own drivers to seamlessly initialize the acquisition modality from within the CDI UI. It does not matter which type of modality is used to acquire the image, or which type of image series that might be taken, the user is always presented with the same interface. CDI will be designed to create a standard DICOM object that conforms to industry standards. The use of DICOM is an absolute necessity to ensure interoperability with current and future imaging systems. CDI will also provide easy-to-use image processing tools that aid providers in analyzing images and making diagnoses. CDI will allow users to enhance the contrast and brightness of an image, reverse image values to show dental caries, and magnify specific areas of concern.

Note: Modifications can be saved, but they are only saved as a copy of the original image. The original image will always remain untouched.

Indications for Use: 21 CFR 807 92(a)(5)

Corporate Dental Imaging (CDI) Application™ is a software device for general dental diagnostic imaging. It controls capture, display, transfer, enhancement, and storage of X-ray dental images from digital imaging systems.

Technological Characteristics: 21 CFR 807 92(a)(6)

Corporate Dental Imaging (CDI) Application™ is a software device that handles and manipulates digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and or printed. In general, a PACS (Picture Archiving and Communication System) is a medical imaging technology which provides storage of, and convenient access to, images from multiple modalities. Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM 3.x (Digital Imaging and Communications in Medicine). Non-image data, such as scanned documents, may be incorporated using consumer industry standard formats like PDF (Portable Document Format), once encapsulated in DICOM. The subject device and predicate device are substantially equivalent in the areas of technical

characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The predicate and subject devices are substantially equivalent in the areas of general function, application, and intended use. Any difference between the two devices does not affect safety or efficacy. The predicate device and the new device are compared below:

Functionality	**Predicate: Xelis DENTAL (K102684)**	**Subject Device: CDI Application™**	**If different, Impact on Safety and or Efficacy**
Computer platform (minimum requirements)	IBM compatible Memory: 1GB Disk: 200MB free hard disk space	IBM compatible CPU: 1 Dual Core Processor Memory: 8GB RAM HDD: C: (OS)=140GB; D: (Data)=2TB	Yes, there are differences. Current computer platforms have these added hardware features to support the operating system, Microsoft Windows 64 bit 2008 R2 Enterprise, and they are for the operating system to run efficiently. The difference does not create new risks and does not impact safety or efficacy as explained in rationale below section 6.1.1 (a) below
Computer Operating System	Microsoft Windows XP/Vista or higher (32bit & 64 bit) Professional	Microsoft Windows 64 bit 2008 R2 Enterprise	Yes, there are differences. The Windows XP and Vista is no longer supported by Microsoft. CDI uses the Microsoft Windows 64 bit 2008 R2 Enterprise operating system. The system has passed testing against pre-determined criteria and the difference does not create new risks and does not impact safety or efficacy.
Enterprise distribution of images and data via Internet or Intranet	Yes	Yes	No differences
Networking Communications Protocol - DICOM 3.x	Yes	Yes	No differences
Image Compression:	No compression or Lossless	No compression or Lossless	No differences
Standard Interfaces - Ethernet	Yes	Yes	No differences
Image Storage- Server & on board hard disk size & compression dependent. Can store to Short or Long Term Archives	Yes	Yes	No differences
Multi-Planar Reformation (MPR) - MPR into any classic planes (axial, sagittal, coronal, oblique planes) and curved and free-draw planar reformation. 3D image-guided reformation on VR, MIP/MinIP	Yes	No	Yes, there are differences. MPR is not a feature that is implemented in the Medical Viewer and there are no claims as such in the CDI device labeling. This feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Virtual Endoscopy - Observe the internal structure using the virtual camera.	Yes	No	Virtual Endoscopy is not a feature that is implemented in the CDI and there are no claims in the CDI device labeling for this

Functionality	Predicate: Xelis DENTAL (K102684)	Subject Device: CDI Application™	If different, Impact on Safety and or Efficacy
			feature. Not having this feature does not create new risks and does not impact safety or efficacy of the subject device.
Reporting - Save, email, DICOM send, or print to standard Windows printers	Yes	No	Yes, there are differences. Reporting - Save, email, DICOM send, or print to standard Windows printers is not a feature implemented in CDI and there are no claims in the CDI device labeling for this feature. This feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Move, rotate, flip and delete template	Yes	Rotate and flip images only	Yes there are differences. The CDI application itself cannot move or delete images. This feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Draw line	Yes	Yes	No differences
Draw arrow	Yes	Yes	No differences
Write text	Yes	Yes	No differences
Measure distance	Yes	No	Yes, there are differences. Measurement is not a feature in the CDI application. This feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Measure angle	Yes	Yes	No differences
Measure area	Yes	Yes	No differences
Print image	Yes	Yes	No differences
2D Image Viewer- 2D image viewer with real-time pan, zoom, centering, windowing, flip, rotation, free layouts, cine and annotation Tools for removal of obscuring anatomy including ROI drawing, ROI dilation and erosion, paint, fence, thresholding, 2D & 3D region growing and balloon. Analytical tools for measuring distance, angle, ROI, grid, table, profile, time-density curve, pixel coordinate, and scale bar.	Yes	2D image viewer - 2D image viewer has the following: real-time pan, zoom, centering, windowing, flip, rotation, free layouts and annotation Tools.	Yes there are differences in the CDI application which has reduced functionality compared to the predicate device. However, these features are not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
MIP/MinIP - maximum intensity projection	Yes	No	Yes there are differences in the CDI application which has reduced

Functionality	Predicate: Xelis DENTAL (K102684)	Subject Device: CDI Application™	If different, Impact on Safety and or Efficacy
			functionality compared to the predicate device. However, this feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Dental volume reformat functions, such as arch/curve, drawing nerve-canal, axis and re-slice based on dental arch	Yes	No	Yes there are differences in the CDI application which has reduced functionality compared to the predicate device. However, this feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Dental implant planning, which provides simulations of implant placement, bone-structure analysis and location of the mandibular canal.	Yes	No	Yes there is a difference. This is not a feature in the CDI application. A feature for simulations of implant placement, bone-structure analysis and location of the mandibular canal is not implemented or claimed. This feature is not required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.
Intended Use[1]	Picture archiving and communication systems (PACS)	Picture archiving and communication systems (PACS)	Yes, there are differences but both systems are a picture archiving and communication systems (PACS) is a combination of hardware and software dedicated to the short and long term storage, retrieval, management, distribution, and presentation of images. Electronic images and reports are transmitted digitally via PACS; this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is DICOM (Digital Imaging and Communications in Medicine). There are differences in the features and functions used in the subject device when compared to the predicate. The subject device has less features. However, the features and functions that are no in the subject device are not

[1] "Intended Use" is the "Objective Intent" for the device of the persons legally responsible for labeling the device. The FDA defines "Intended Use" as: The term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by their expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such representatives. It may be shown by the offering or the using of the device, with the knowledge of such persons or their representatives, for a purpose for which it is neither labeled nor advertised. (21 CFR 801.4)

Functionality	Predicate: Xelis DENTAL (K102684)	Subject Device: CDI Application™	If different, Impact on Safety and or Efficacy
			required to meet the subject device intended use. The system has been tested against pre-determined criteria and passed. The difference does not create new risks and does not impact safety or efficacy.

Nonclinical Testing:

The Corporate Dental Imaging (CDI) Application™ device has been assessed and tested at the factory and has passed all in-house testing criteria. The Verification & Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the Corporate Dental Imaging (CDI) Application™ software in each operational mode and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met. If the device is installed by the manufacturer, integration and installations verification tests will be conducted against acceptance criteria prior to being released to the user facility.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the Corporate Dental Imaging (CDI) Application™ contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of general function, application, and intended use. The subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. Nonclinical tests demonstrate that the device is safe and effective for its' intended use. Therefore, the Corporate Dental Imaging (CDI) Application™ is substantially equivalent to the predicate device.