Infinitt Healthcare Co., Ltd.
℅ Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

April 14, 2020

Re: K193369
Trade/Device Name: Xelis Dental 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 7, 2020
Received: March 11, 2020

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. 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 post marketing 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193369

Device Name
Xelis Dental 2.0

Indications for Use *(Describe)*

Xelis Dental 2.0, is a standard PC based software application used for the display and 3D visualization of DICOM medical image files from CT or CBCT. Xelis Dental 2.0, is intended to be used by authorized healthcare professionals such as radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, review, store, print, distribute images to assist in diagnosis. Xelis Dental 2.0, also provides 3D visualization, 2D analysis and various MPR (Multi-Planar Reconstruction) functions and can be used as a preoperative software application used for the planning and verification of dental implants. There is no population and age restrictions for patients using this software. Xelis Dental 2.0, is not intended for use with or for the primary diagnostic interpretation of Mammography images.

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.

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

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510(k) Summary

K193369

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

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Date Prepared: November 14, 2019

II. DEVICE

Name of Device: Xelis Dental 2.0
Common or Usual Name: Picture Archiving Communications System
Classification Name: system, image processing, radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

III. PREDICATE DEVICES

Primary Predicate Device: Xelis Dental, K102684, by INFINITT Healthcare Co. Ltd., CFR 892.2050, Product Code LLZ.

IV. DEVICE DESCRIPTION

Xelis Dental 2.0, is a software device used for viewing and manipulating DICOM-compliant images from CBCT (Cone beam computed tomography). Xelis Dental 2.0 is an advanced, easy-to-use dental software providing various tools to dental facilities. Xelis Dental 2.0, provides a practical tool for 3D (three dimensional) and 2D (two dimensional) viewing to optimize dental treatment planning and placement. This stand-alone, Windows-compatible software provides 3D volume rendering (VR), multi-planar reconstruction (MPR) and image segmentation. Xelis Dental 2.0, offers dental implant planning, canal draw, bone density assessment, segmentation and report functionalities. The subject device (Xelis Dental 2.0) is based upon the predicate device, Xelis Dental, (K102684). Xelis Dental 2.0 has updated the software from the predicate to reflect current computer technology and also has a number of new/improved functions. Both the subject device and the predicate are from INFINITT Healthcare Co. Ltd.

V. INDICATIONS FOR USE

Xelis Dental 2.0, is a standard PC based software application used for the display and 3D visualization of DICOM medical image files from CT or CBCT. Xelis Dental 2.0, is intended to be used by authorized healthcare professionals such as radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, review, store, print, distribute images to assist in diagnosis. Xelis Dental 2.0, also provides 3D visualization, 2D analysis and various MPR (Multi-Planar Reconstruction) functions and can be used as a

preoperative software application used for the planning and verification of dental implants. There is no population and age restrictions for patients using this software.
Xelis Dental 2.0, is not intended for use with or for the primary diagnostic interpretation of Mammography images.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and primary predicate are both PACS, which are indicated for dental medical image management, review, and data distribution. Both systems have been developed to replace traditional film handling in radiology. The subject device and the predicate device are substantially equivalent in the areas of general function, application, and intended use. Any differences between the predicate and the new device has no impact on safety or efficacy of the new device and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

Functionality	Subject Device XELIS DENTAL 2.0	XELIS DENTAL K102684 Predicate	If different, Impact on Safety and or Efficacy
Computer platform & OS (minimum requirements)	Microsoft Windows 7/ Windows 10 (32bit & 64 bit) Professional. IBM compatible Memory: 8GB or more Disk: 2GB free hard disk space	Microsoft Windows XP/Vista or higher (32bit & 64 bit) Professional IBM compatible Memory: 1GB Disk: 200MB free hard disk space	Difference: Computer technology advancements since 2010 and does not raise any new potential or increased safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
Enterprise distribution of images and data via Internet or Intranet	Yes	Yes	No differences
Networking Communications Protocol - DICOM 3.0	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 reformation on VR, MIP/MinIP	Yes	Yes	No differences
Image Layout	Yes	No	Difference: The subject device can be configured for various user views, e.g. 1 up to 4 up including panoramic views. The adding of these features befits User

510(k) Summary

Functionality	Subject Device XELIS DENTAL 2.0	XELIS DENTAL K102684 Predicate	If different, Impact on Safety and or Efficacy
			viewing and does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
Draw lines or arrows	Yes	Yes	No differences
Write text	Yes	Yes	No differences
Measure distance, angle and area.	Yes	Yes	No differences
Print image	Yes	Yes	No differences
Common tools for zoom pan, windowing, rotate invert, VOI (Volume of Interest), text overlay reset all	Yes	Yes	No differences
Common toolbar edits (tool show/hide)	Yes	No	Difference: The common toolbar can be shown or hidden and also be customized by the User. The features and functions of the Xelis Dental2.0 are described in labeling so the user will be aware of the system functionality. The difference does not raise any new or additional potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
MIP/MinIP – maximum/minimum intensity projection	Yes	Yes	No differences
Dental volume reformat function, such as arch/curve, drawing nerve-canal, axis and resliced based on dental arch	Yes	Yes	No differences
Implant planning, which provides simulations of implant placement, bone-structure analysis and location of the mandibular canal	Yes	Yes	No differences
Reporting - save, DICOM send, or print to standard Windows printers	Yes	Yes	No differences
Real size printing	Yes	Yes	No differences
Report PDF export	Yes	Yes	No differences
Template based report	Yes	Yes	No differences
Implant report	Yes	No	Difference: The User can define a default report template and implant report template, which is populated with predetermined information as selected by the User. The feature is described in labeling so the user will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.

510(k) Summary

Functionality	Subject Device XELIS DENTAL 2.0	XELIS DENTAL K102684 Predicate	If different, Impact on Safety and or Efficacy
CD/DVD/USB-burning	Yes	Yes	No differences
Project save	Yes	Yes	No differences
Annotation List function	Yes	No	Difference: This feature will enable the User to check and manage the information of annotations drawn on the image shown in the layout. Selecting an item in the list moves the images to the location where the annotation is drawn. The feature is described in labeling so the user will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
DICOM Report Send	Yes	No	Difference: Reports can be sent as PDF DICOM format. The feature is described in labeling so the user will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Arch List function	Yes	No	Difference: Images can be analyzed by making a Cross-sectional View setting the vertical plane along the curve of the arch. The feature is described in labeling so the user will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Bone density color map	Yes	No	Difference: Colors can be assigned to different bone density and viewed. The feature is described in labeling so the user will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Canal Thickness function	Yes	No	Difference: The Nerve Drawing function is useful when consulting patients. Xelis Dental offers Canal Draw and Canal Manager functions. The feature is described in labeling so the user will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Auto Project Save function	Yes	No	Difference: Automatically save the working state. Auto-saved items can be viewed in the worklist and can be configured in detail through options. The feature is described in labeling so the user

Functionality	Subject Device XELIS DENTAL 2.0	XELIS DENTAL K102684 Predicate	If different, Impact on Safety and or Efficacy
			will be aware of the system functionality. The difference does not raise any new or potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.

VII. PERFORMANCE DATA

Nonclinical Testing:

The Xelis Dental 2.0, PACS has been assessed and tested at the factory and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by Xelis Dental 2.0, 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.

Summary:

Based on the performance as documented in the Validation Testing, Xelis Dental 2.0, was found to have a safe and effectiveness profile that is similar to the predicate device.

The following Standards were used to develop Xelis Dental 2.0, and the device has met all the requirements listed in the Standards except for inapplicable requirements:

- ISO14971:2007/(R)2010 (Corrected 4 October 2007), Medical devices - Applications of risk management to medical devices, FDA FR Recognition # 5-40.
- NEMA PS 3.1 - 3.20 (2016, Digital Imaging and Communications in Medicine (DICOM) Set, FDA FR Recognition # 12-300.
- IEC 62304:2006, Medical device software - Software life cycle processes, FDA FR Recognition # 13-32.
- FDA Guidance on Cyber Security: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Document Issued on: October 2, 2014
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005

VIII. CONCLUSIONS

The 510(k) Pre-Market Notification for Xelis Dental 2.0, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The new device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use 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 as safe, as effective, and performs comparably to the predicate devices.