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

February 13, 2020

Re: K193498
Trade/Device Name: INFINITT RT PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 31, 2019
Received: December 17, 2019

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 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

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)*
K193498

Device Name
Infinitt RT PACS

Indications for Use *(Describe)*

INFINITT RT PACS is a software medical device intended to be used for reviewing and assessment of DICOM based datasets which may occur in a radiotherapy environment. It is used by qualified specialist to load and display data generated by different DICOM devices including: RT-STRUCTURE, RT-PLAN, RT-DOSE, RT-IMAGE, CR, CT, MR and PET. The software can connect to a HIS and provides the radiotherapy specialist with the necessary visualization and image manipulation tools to review, present or compare DICOM, RT related datasets including the geometrical super imposition of 3D plan data. INFINITT RT PACS, is intended for reviewing purposes only and is not capable to generate new or modified RT plan data. Users of INFINITT RT PACS, should be trained medical professionals including, radiologists, oncologists, physicians, medical technologists, and dosimetrists. Users should be familiar with the different sources of input data (such as images, structure sets, treatment plans, and calculated dose) as well as how to understand and interpret derived metrics (e.g., dose-volume histograms).
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that offers at least 5 Mega-pixel resolution and meets other technical specifications reviewed and accepted by FDA. INFINITT RT PACS, is not intended for diagnostic image review on mobile devices.

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.

510(k) Summary

K193498

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: December 9, 2019

II. DEVICE

Name of Device: Infinitt RT PACS
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: **ProKnow DS (K182855)**, by ProKnow LLC, CFR 892.2050, Product Code LLZ.

IV. DEVICE DESCRIPTION

Infinitt RT PACS, is a radiation therapy image Management solution dedicated to the oncology department. By using Infinitt RT PACS, the treatment planning system of various vendors can be stored and managed. It also transfers DICOM RT type plan images and information to EMR through HL7or database links.

Infinitt RT PACS, provides the function to acquire and view DICOM data generated from RTP (Radiotherapy Planning) System in the form of DICOM C-Store. Supported data includes CT (Computerized Tomography) DICOM image, DICOM RT PLAN data, DRR (Digitally Reconstruct Radiography) image and DICOM RT-Structure, dose information of DICOM RT-Dose and DVH (Dose-Volume Histogram) data. In addition, it supports Axial, Coronal, Sagittal view to check the location of the corresponding Axial CT image and dose distribution to Coronal, Sagittal View through scout line.

Infinitt RT PACS, provides DICOM conformant services for both short and long-term image storage and retrieval of digital image data. The application uses DICOM as the interface to the external world and enables interoperability between different devices.

Infinitt RT PACS, accepts DICOM association requests for the purpose of storing images and for query and retrieval of images. It also initiates DICOM association requests for the purpose of sending images to an external application entity.

V. INDICATIONS FOR USE

INFINITT RT PACS is a software medical device intended to be used for reviewing and assessment of DICOM based datasets which may occur in a radiotherapy environment. It is used by qualified specialist to load and display data generated by different DICOM devices including: RT-STRUCTURE, RT-PLAN, RT-DOSE, RT-IMAGE, CR, CT, MR and PET. The software can connect to a HIS and provides the radiotherapy specialist with the necessary visualization and image manipulation tools to review, present or compare DICOM, RT related datasets including the geometrical super imposition of 3D plan data.

INFINITT RT PACS, is intended for reviewing purposes only and is not capable to generate new or modified RT plan data. Users of INFINITT RT PACS, should be trained medical professionals including, radiologists, oncologists, physicians, medical technologists, and dosimetrists. Users should be familiar with the different sources of input data (such as images, structure sets, treatment plans, and calculated dose) as well as how to understand and interpret derived metrics (e.g., dose-volume histograms).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA cleared monitor that offers at least 5 Mega-pixel resolution and meets other technical specifications reviewed and accepted by FDA. INFINITT RT PACS, is not intended for diagnostic image review on mobile devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and predicate are both PACS, which are indicated for 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 subject device has no negative impact on the device safety or efficacy and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

Functionality	**Subject Device INFINITT RT PACS**	**Predicate Device ProKnow DS (K182855)**	**If different, Impact on Safety and or Efficacy**
Hardware Requirements	OS: Windows 7 or higher Processor: Intel Core i5 or higher Memory: 4GM or more Graphic card: 1920x1080, 32bpp	OS: Windows 7, 10, and macOS High Sierra Processor: Dual Core2.2+ GHz Intel or equivalent processor Memory: 8GB Graphic card: WebGL compatible graphic card 1280x800 effective display resolution (1900x1080 recommended)	Yes, there are differences in the computer requirements which are dependent upon software development and implementation. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Enterprise distribution of images and data via Internet or Intranet	Yes	Yes	No differences
Networking Communications Protocol - DICOM 3.1	Yes	No	Yes, there are differences. The subject device uses the DICOM 3.1 FDA recognized standard for network communications and device interoperability. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.

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Functionality	Subject Device INFINITT RT PACS	Predicate Device ProKnow DS (K182855)	If different, Impact on Safety and or Efficacy
Image Compression	No compression	No compression	No differences
Supported DICOM Standard SOP Classes	CT Image Storage MR Image Storage PET Image Storage RT Dose Storage RT Structure Set Storage RT Plan Storage RT Ion Plan Storage RT Image Storage Secondary Capture Image Storage	CT Image Storage MR Image Storage RT Dose Storage RT Structure Set Storage RT Plan Storage RT Ion Plan Storage Spatial Registration	Yes, there are differences in the supported DICOM SOP Classes. The subject device complies with the FDA recognized DICOM Standard and has been tested. The product functions are explained in labeling and does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Worklist	Search Filter Search Criteria Examined Patient History Patient List Latest Plan List	Patient List Filter Workspace Filter Patient Patient Collection	Yes, the difference is how the data is retrieved. This does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Image Display Function	Slice Navigation Window/Level Zoom Zoom to Selection Pan Reset	Slice Navigation Window/Level Zoom Zoom to Selection Zoom to Fit Pan Probe	There are differences where the subject device does not have the exact features of the predicate. The subject device has been validated and features and functions are documented in the device labeling. The differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Annotation/Measurement	Yes	No	The subject device supports annotation/measurement. The subject device has been validated and features and functions are documented in the device labeling. The difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Multi-Planar Reformation	Axial, Sagittal, Coronal	Axial, Sagittal, Coronal	No differences
3D Volume Rendering	Yes	No	The subject device supports 3D Volume Rendering, has been validated and features and functions are documented in the device labeling. The difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Image Capture Tool	Yes	No	The subject device supports an Image Capture Too, has been validated, and features and functions are documented in the device labeling. The difference does not raise any new potential safety risks and

510(k) Summary

Functionality	Subject Device INFINITT RT PACS	Predicate Device ProKnow DS (K182855)	If different, Impact on Safety and or Efficacy
			therefore, we believe there is no impact on safety or efficacy for the subject device.
Contouring Tool	No	Yes	The subject device does not support a Contouring Tool. The subject device has been validated and features and functions are documented in the device labeling. The difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Display ROI	Yes	Yes	No differences
Plan Information	Yes	Yes	No differences
Beam Information	Yes	Yes	No differences
Display Dose Distribution	Yes	Yes	No differences
Isodose Level Setting	Yes	Yes	No differences
Dose Volume Histograms	Yes	Yes	No differences
Scorecards	Yes	Yes	No differences
Plan Summation	Dose Composition based on the image fusion	Dose Composition based on the spatial registration	The difference on how each device handles Plan Summation. The subject device has been validated and the difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Plan Comparison	Yes	No	The subject device supports Plan Comparison, has been validated and features and functions are documented in the device labeling. The difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
Display DRR/Portal/Simulator Image	Yes	No	The subject device supports DRR/Portal/Simulator Image, has been validated and features and functions are documented in the device labeling. The difference does not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the subject device.
HIS Interface	Yes	No	The subject device supports HIS Interface. The subject device has been validated and features and functions are documented in the device labeling. The difference does not raise any new 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 Infinitt RT PACS, has been assessed and tested at the factory and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate output functions, and actions performed by Infinitt RT PACS, 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, Infinitt RT PACS, was found to have a safe and effectiveness profile that is similar to the predicate device.

The following Standards were used to develop Infinitt RT PACS, 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 Infinitt RT PACS, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject 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.