TechHeim Co., Ltd.
℅ Mr. JeongKeun Kim
RA Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
SEOUL, 08390
SOUTH KOREA

July 8, 2021

Re: K211480
Trade/Device Name: NubeX
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 6, 2021
Received: May 12, 2021

Dear Mr. Kim:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211480

Device Name
NubeX

Indications for Use *(Describe)*
NubeX, PACS is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography.
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g physicians, radiologists, nurses, and medical technicians.

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

K211480

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

Date: Jun 09, 2021

1. INFORMATION

1.1 Submitter Information

- Submitter Name: TechHeim Co., Ltd
- Address
  : 21, Banpo-daero 24-gil, Seocho-gu, Seoul, 06648, Republic of Korea
- Telephone Number: +82-2-2028-0733
- Fax: +82-2-2028-0734
- E-mail: wylee@techheim.com

1.2 Contact Person

- Name: JeongKeun Kim (RA Consultant / KMC, Inc.)
- Address: Room 1709, 123, Digital-ro 26-gil, Guro-gu, Seoul, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: jkkim@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: NubeX

2.2 Regulation Name: Medical Image Management and Processing System.

2.3 Classification Name: system, image processing, radiological

2.4 Product Code: LLZ

2.5 Regulation number: 21 CFR892.2050

2.6 Device Class: Class II

2.7 Classification Panel: Radiology

3. PREDICATE DEVICE

Manufacturer	INFINITT CO., LTD.
Device Name	INFINITT ULite

(Trade Name)	
510(k) Number	K163290
Regulation name	Picture archiving and communications system
Regulation number	21 CFR892.2050
Product code	LLZ
Classification	Class II

4. SUBJECT DEVICE DESCRIPTION

NubeX is a based on the predicated Picture Archiving and Communication system (PACS) device (INFINITT ULite, K163290).
NubeX is for displays medical images and data from various imaging sources, and from other healthcare information sources. Medical images and data can be displayed, communicated, stored, and processed.
Among part of image processing, there are different functions than predicated device (INFINITT ULite, K163290).

In NubeX, provide image stacking function and 3D cursor function. In case of stacking, after putting the mouse point on an image, you can use the mouse wheel to view the previous or next image of the current one in the series. Stacking shows images within the series. Thus, although the last image currently shows up and the mouse wheel moves down, the last image does not get changed.

In case of 3D cursor, after turning on the "3D Cursor" button and selecting an image or stack window, if you use the mouse left button to click and drag on the image, you can see the "X" mark and move the mark to any direction. At that time, you can see the images which are on the mark point in the 3D space. For example, when you click and drag on a sagittal image, you can see the images axial images that are on the mark point in the 3D space.

Other than that, the functions basically provided as PACS are the same as those of predicated devices and the additional PACS features don’t present any risk to device safety.

5. INTENDED USE

NubeX is a Picture Archiving and Communication system (PACS) for displays medical images and data from various imaging sources, and from other healthcare information sources. Medical images and data can be displayed, communicated, stored, and processed.
Typical users of this system are trained professionals such as physicians, radiologists, radiographer, and other qualified medical professionals.

6. SUBSTANTIAL EQUIVALENCE

NubeX is substantially equivalent to the predicate devices (INFINITT ULite, K163290). The following table is presented to demonstrate substantial equivalence.

	Subject Device	Predicate Device
Manufacturer	TechHeim Co., Ltd	INFINITT CO., LTD.
Device Name	NubeX	INFINITT ULite
510(k) number	K211480	K163290
Classification Product Code / Regulatory Number	Product code: LLZ Regulatory number: 21 CFR 892.2050	Product code: LLZ Regulatory number: 21 CFR 892.2050
Regulatory Class	Class II	Class II
Indications for Use	NubeX, PACS is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g physicians, radiologists, nurses, and medical technicians.	INFINITT ULite, PACS is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA. Typical users of this system are trained professionals, e.g physicians, radiologists, nurses, and medical technicians.
Technological characteristics	NubeX, device is a software product that handles 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	INFINITT ULite™ device is a software product that handles 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 printed.	human intervention interprets images and information being displayed and printed.
Software environment	OS: Windows 10 (64bit) / Chrome (64bit) v67 +	OS: over the Microsoft Windows 7
Resolution	Minimum specification 32bit Color Display & 1920x1080 resolution Recommend specification 32bit Color Display & 1920x1080 or higher resolution	1280 x 1024
Main Function	· Log in · Worklist – Search filter · Worklist – Open image · Worklist – exam list · Worklist – Report · Worklist - Series · Viewer – View exam · Viewer – Control View-window · Viewer – view mode (large) · Viewer – view mode (real-resolution) · Viewer – view mode (highlight) · Viewer – Stacking · Viewer – Changing layout · Viewer – Window/Leveling · Viewer – Comparative study · Viewer – Preset filter · Viewer – Zooming · Viewer – Panning · Viewer – Rotation · Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) · Viewer – Advanced image operation · Viewer – Scout line · Viewer – Sharpening · Viewer – Annotation · Viewer – Cine	· Log in · Worklist – Search filter · Worklist – multiple selection · Worklist – Open image · Worklist – Series list · Worklist – Configuration · Viewer – display image · Viewer – multiple series · Viewer – Main tab (exam) · Viewer – Toolbar · Viewer – Thumbnail · Viewer – Exam list · Viewer – combine mode · Viewer – change series list · Viewer – display layout · Viewer – selecting image · Viewer – adjust window width/level · Viewer – window preset · Viewer – inverting image color · Viewer – measure · Viewer – annotation · Viewer – Spine labeling · Viewer – Pan · Viewer – Magnifying Glass · Viewer – Zoom · Viewer – Rotation/ Flip · Viewer – Scout line · Viewer – Overlaying · Viewer – Cine mode · Viewer – Report
Operation feature	- Web environment based PACS - Viewing and handling DICOM medical image - Review, modify and approve study located in a server	- Web environment based PACS - Viewing and handling DICOM medical image - Review, modify and approve study located in a server
Prescription or OTC	Prescription	Prescription

6.1 Difference between the subject device and the predicates devices

1) Software environment

: The subject device has a different software O.S and web environment.
This difference does not raise any problems in the safety and effectiveness when we use NubeX for displays medical images and data from various imaging sources, and from other healthcare information sources.
Medical images and data can be displayed, communicated, stored, and processed.

2) Resolution

: The subject device has a different displayed resolution.
The result show that these difference does not raise any problem for displays medical images and data from various imaging sources, and from other healthcare information sources.
Medical images and data can be displayed, communicated, stored, and processed in the safety and effectiveness.

6.2 Equivalence between the subject device and the predicates devices

1) Product code

: The proposed product code of the subject device is “LLZ”. It is the same classification name as the predicate device.

2) Indications for use

: For indications for use, NubeX is a Picture Archiving and Communication system (PACS) for displays medical images and data from various imaging sources, and from other healthcare information sources. Medical images and data can be displayed, communicated, stored, and processed.
Typical users of this system are trained professionals such as physicians, radiologists, radiographer, and other qualified medical professionals.

3) Function

: Both devices (subject device and predicate device) are composition to Worklist and Viewer to show the Medical images and data which can be displayed, communicated, stored, and processed.

4) Operation feature

: Both devices (subject device and predicate device) are operated by web PACS environment for displays medical images and data from various imaging sources, and from other healthcare information sources through the DICOM.

5) Prescription or OTC

: Both devices (subject device and predicate device) are prescription medical device. It is the same.

7. Performance Data

The following performance data were provided to support the substantial equivalence determination.

Non-clinical performance data

Non-clinical tests relied on this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- Software Verification and Validation
  IEC 62304:2015, Medical Device Software - Software Life Cycle Processes

- Cybersecurity Verification and Validation
  FDA guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

- Function Test
  Internal Standards,
  The complete system configuration has been tested at the factory and the device has passed all in-house pre-determined testing criteria without significant failures. The data presented in the submission demonstrates that NubeX performs all required actions according to the functional requirements specified in the Software Requirements Specification and the User Manual with no errors that had an impact on safety or efficacy.

8. CONCLUSION

Under the comparing substantial equivalence between the subject device and the predicate device, there are the same points such as product code, indications for use, operation, performance and technological characteristics.
Although there are some differences (Software environment, Language, Resolution), the device function and internal test (function test) are supported to the safety and effectiveness of the subject device.
In this regard, we conclude that the subject device is substantially equivalent to the predicate device.