Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

March 1, 2019

Re: K183478
Trade/Device Name: ClearON Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 13, 2018
Received: December 17, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183478

Device Name
ClearON Mobile

Indications for Use *(Describe)*
ClearOn Mobile software carries out the image processing and administration of medical X-ray data which includes adjustment of window leveling, rotation, zoom, and measurements. ClearOn Mobel is not approved for mammography and is meant to be used by qualified medical personnel only. ClearOn Mobile is complying with DICOM standards to assure optimum communications between network systems.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary-K183478

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

Date 510K summary prepared: December 13, 2018

Submitter's Name, address, telephone number, a contact person:

Submitter's Name : Rayence Co., Ltd.
Submitter's Address: 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Submitter's Telephone: **+**82-31-8015-6459
Contact person: Mr. Kee Dock Kim / RA Team Manager / +82-31-8015-6459
Official Correspondent: Dave Kim **(**davekim@mtech-inc.net**)**
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
Fax: +713-583-8988

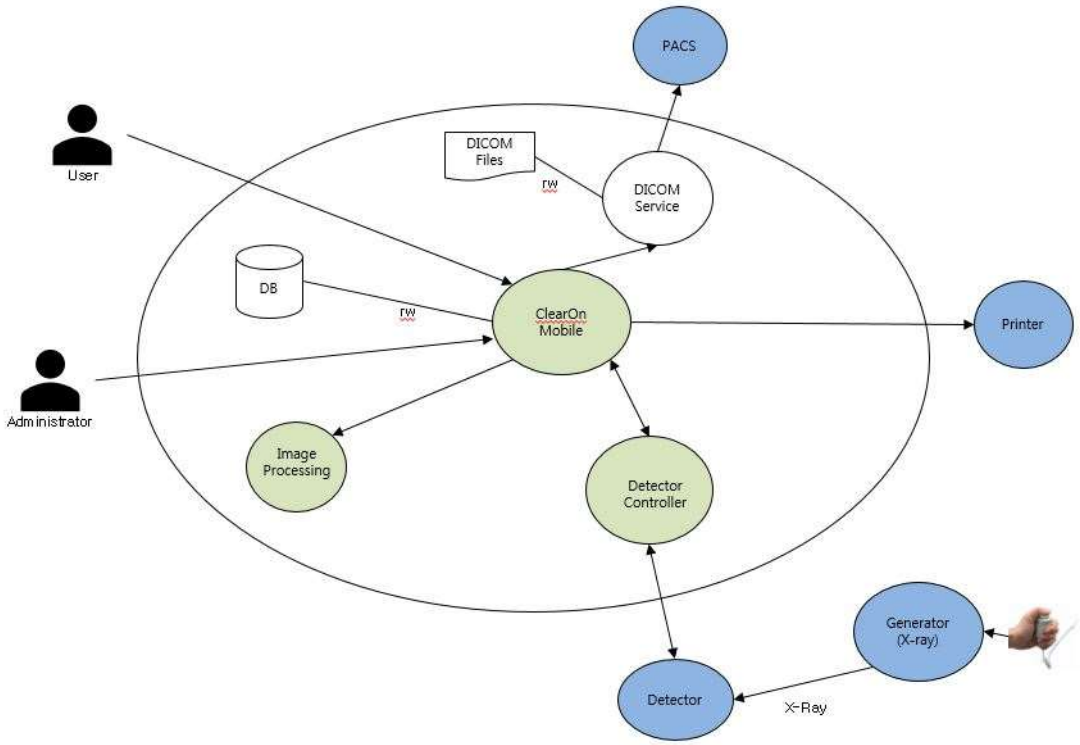
Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Type of 510k Submission: Special
Trade/proprietary name: ClearOn Mobile
Common Name: Medical Image Processing Software
Regulatoin number: 21 CFR 892.2050
Classification Name : Picture archiving and communications system
Product Code: LLZ

Predicate device
Manufacturer: Rayence Co., Ltd.
Device Name : XmaruView V1
510(k) Number: K160579 (Decision Date – Apr 08, 2016)
Common Name: Medical Image Processing Software
Regulatoin number: 21 CFR 892.2050
Classification Name : Picture archiving and communications system
Product Code: LLZ

2. Device Description

ClearON Mobile provides easy touch based user interface to perform diagnosis of digital radiograph images displayed on ClearOn Mobile. ClearON Mobile receives digital images from a flat panel detector and a X-ray generator. The software also manages patient data, stores and transfers diagnostic images in an internal database.
It supports DICOM image file format which allows interoperability with other Radiography equipment in network environment.



3. Indication for use

ClearOn Mobile software carries out the image processing and administration of medical X-ray data which includes adjustment of window leveling, rotation, zoom, and measurements. ClearOn Mobel is not approved for mammography and is meant to be used by qualified medical personnel only. ClearOn Mobile is complying with DICOM standards to assure optimum communications between network systems.
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4. The Main Functions of ClearON Mobile

The major functions of ClearON Mobile are as follows.

- Automatic transfer of patient information and image data through the DICOM Worklist.
- Auto Query that searches the Worklist server at each designated interval and handle new works rapidly and efficiently.
- Display an image within a short period of time after taking an image.
- Enables a user to conduct a variety of functions, including DICOM image transmission, printing, and Worklist search.
- Provides image editing functions, including Contrast, Invert, Rotate, ROI, and Windowing.
- Image management functions: test creation, modify and delete information, move and delete image, and image storage management.
- Supports DICOM 3.0, data transfer to the PACS server, print and Worklist jobs.

5. Interoperation products

ClearON Mobile are compatible with the following detectors and generators:

- Rayence's Detector
- Generator
  - EDITOR HFe 501(Spellman)
  - CMP200(CPI)
  - SYNERGY(SUMMIT)

6. Substantial Equivalence

ClearON Moblie SW and the predicate device, XmaruView V1 image viewer software are substantially equivalent, having the same / similar indications for use and functionalities such as image processing, windowing, zoom, rotation, contrast, brightness, inverting view, annotation, DICOM worklist, DICOM store and DICOM print. The differences are cosmetic, such as layout of UI and touch screen interface for the ClearON Mobile. Both subject device and predicate device are categorized as the product code LLZ; equivalence between the subject and predicate device is evident.

The pre and post image processing algorithm is identical for both ClearON Mobile and XmaruView V1.

The differences between the subject and predicate device are as follows:
1) ClearON Mobile is compatible with a Window 10 based touch screen device. For example, zoom, drawing and measurement can be done with touch of a finger(s) in stead of a conventional keyboard/mouse input.

7.Summary of Performance Testing

1) Nonclinical Testing:
   The complete system configuration has been assessed and tested by the manufacturer and passed all testing acceptance criteria. The software validation test was designed to evaluate all input functions, output functions, and actions performed by ClearOn Mobile. Each operational mode and the processes are documented in the Software Validation Report.
   The validation testing verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

2) Safety and Performance Data:
   The SW validation and risk analysis based on FMEA were conducted. The risks identified have been mitigated and any residual risks were evaluated and accepted.

   - IEC 62304 Medical device software – Software life-cycle processes : 2006
   - ISO 14971 Medical Devices – Application of risk management to medical device : 2007

8. Conclusions

None of the modifications alter the Indications for Use in a significant way, nor the fundamental scientific technology, and do not introduce any new technology. Therefore, it is our opinion that the ClearON Mobile described in this submission is substantially equivalent to the predicate device, XmaruView V1.