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

July 13, 2015

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

Re: K151014
Trade/Device Name: AURA DR 43C-AG Digital Flat Panel X-ray Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 17, 2015
Received: June 18, 2015

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. 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)*
K151014

Device Name
AURA DR 43C-AG
Digital Flat Panel X-ray Detector

Indications for Use *(Describe)*

The AURA DR 43C-AG detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

SECTION 07

# 510(k) SUMMARY

## 1. Traditional 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date 510K summary prepared : June 17, 2015

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

| | |
|---|---|
| Submitter's Name : | AbyzR Co., Ltd. |
| Submitter's Address: | #63-27, Geumgok-ro, Dongtan-myeon, Hwaseong-si, Gyeonggi-do, 445-811, Korea |
| Submitter's Telephone: | Tel:+ 82-70-8680-4100 / Fax: +82-70-8244-1177 |
| Contact person: | Mr. John Lim / Sr. Manager (johnlim0107@abyzr.com) |

| | |
|---|---|
| Official Correspondent: | Dave Kim, MBA |
| Address: | 8310 Buffalo Speedway, Houston, TX 77025 |
| Telephone: | +713-467-2607 |
| Fax: | +713-583-8988 |
| Email: | davekim@mtech-inc.net |

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

| | |
|---|---|
| Trade/proprietary name: | AURA DR 43C-AG |
| Regulation Name: | Stationary X-ray System |
| Regulation Number: | 21 CFR 892.1680 |
| Regulatory Class: | II |
| Product Code: | MQB |

| Predicate Device | | |
|---|---|---|
| Manufacturer | : | Samsung Mobile Display Co., Ltd |
| Device | : | LLX240AB01 |
| Regulation Name | : | Stationary X-ray System |
| Regulation Number | : | 21 CFR 892.1680 |
| Product Code | : | MQB |
| 510(k) Number | : | K102587 |
| Decision Date | : | DEC 1, 2010 (Regulation Name Revised on Aug 23, 2013) |

## 2. Device Description

AURA DR 43C-AG is a digital X-ray flat panel detector which has 43㎝ x 43㎝ imaging area and communicates with a wired communication feature, Giga-bit Ethernet communication method through connecting a tether cable. The device intercepts x-ray photons and the scintillator (Gadox:Tb) and emits visible spectrum photons that illuminate an array of photo (a-SI) detector that creates electrical signals. After the electrical signals are generated, it is converted to digital values, and the images will be displayed on the monitor. This device should be integrated with an operating PC and an X-Ray generator. It can digitalize x-ray images and transfer them for radiography diagnostics. Advanced digital image processing allows considerably efficient diagnosis, all kinds of information management, and sharing of image

information on network.

## 3. Indications for Use

The AURA DR 43C-AG detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography.

## 4. Summary of Design Control Risk management

The AURA DR 43C-AG detector has been developed to meet the critical functional requirements and international safety standards. The risks and the hazardous impact of the device design were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the device design and production phase were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design and production were successfully mitigated and accepted.

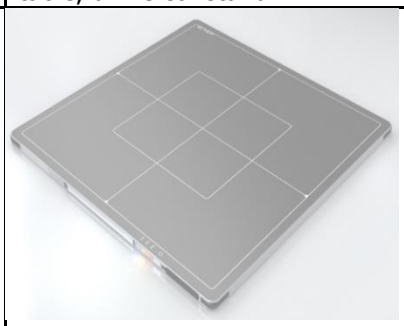
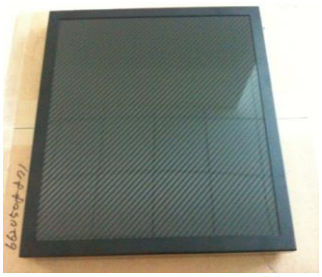
## 5. Summary of the technological characteristics of the device compared to the predicate device:

The AURA DR 43C-AG detector described in this 510(k) has similar indications for use and technical characteristics as the predicate device, LLX240AB01 digital flat panel X-ray detector manufactured by Samsung Mobile Display Co., Ltd.

## 6. Substantial Equivalence

The AURA DR 43C-AG detector and components conform to the FDA recognized standards as like the predicate device. Based on the recognized standard conformity evidences related to electro-, mechanical-, software-,nonclinical-, and risk management, it is confirmed that AURA DR 43C-AG is substantially equivalent to the predicate device.

| **Characteristic** | Proposed<br>AbyzR<br>AURA DR 43C-AG | Proposed<br>Samsung Mobile Display<br>LLX240AB01 | Remark |
|---|---|---|---|
| **510(k) number** | - | K102587 | |
| **Intended Use** | The AURA DR 43C-AG detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography. | LLX240AB01 Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography. | Same |

| | | | |
|---|---|---|---|
| **Detector Type** | Amorphous Silicon, TFT | Amorphous Silicon, TFT | Same |
| **scintillator** | Gadox:Tb | Gadox:Tb | Same |
| **Imaging Area** | 17 x 17 inches | 17 x 17 inches | Same |
| **Pixel matrix** | 3072 x 3072 (9.4 million) | 3072 x 3072 (9.4 million) | Same |
| **Pixel pitch** | 140 μm | 143 μm | Similarity |
| **Resolution** | 3.5 lp/mm | 3.5 lp/mm | Same |
| **A/D conversion** | 16 bit | 14 bit | Similarity |
| **Grayscale** | 16384 (14bit) | 16384 (14bit) | Same |
| **Data output** | RAW<br>*The RAW files are convertible into DICOM 3.0 by console S/W | RAW<br>*The RAW files are convertible into DICOM 3.0 by console S/W | Same |
| **Dimensions** | 460 x 460 x 15 mm | 500 x 496.6 x 45 mm | Similarity |
| **Application** | General Radiology system<br>Available with upright stand, table, universal stand | General Radiology system<br>Available with upright stand, table, universal stand | Same |
| **picture** |  |  | Similarity |

When compared to the predicate device (K102587), the AURA DR43C-AG presented in this submission has very similar characteristics as the predicate device in terms of:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Communication Method

There are no significant difference between the AURA DR43C-AG and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

## 7. Performance Testing/Data

To minimize electrical and mechanical hazards, AbyzR CO., LTD. adheres to recognized and established industry practice, and all equipment complies with the relevant FDA and international standards. For example, electrical, mechanical, environmental safety and performance testing according to standard IEC

60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) was performed and EMC testing was conducted in accordance with standard IEC 60601-1-2: 2007, EN 60601-1-2:2007

Through verification and validation activities, the safety and effectiveness of AURA DR 43C-AG is verified and validated. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or concerns or identify new risks.

The instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

## 8. Description of non-clinical tests.

**- Non-clinical study**
The non-clinical performance testing constrains that the main physical values for comparison of X-ray devices like DQE, MTF NPS are basically equivalent or performed better compared to the predicate device LLX240AB01 (K102587). The results show that AURA DR 43C-AG offers better resolution performance than LLX240AB01 at 0 ~ 3.5lp/mm spatial frequencies. Moreover, the ability of AURA DR 43C-AG to utilize the input image signal is more efficient than LLX240AB01 at same patient exposure.

**-Electrical safety and EMC**
AURA DR43C-AG has been tested for electrical safety standard IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 *2007) + AM1 (2012) and electromagnetic compatibility IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012).

The software validation and verification testing was also performed. The results of nonclinical testing indicate that the AURA DR 43C-AG detector is as safe and effective as the predicate device.

Compliance evidences were submitted for the following standards:

- IEC 60601-1: Test Report issued by 3rd party testing lab
- IEC 60601-1-2: Test Report issued by 3rd party testing lab
- ISO 14971: Risk management file

## 9. Clinical tests

Clinical testing is not necessary to support substantial equivalence of AURA DR 43C-AG with regard to LLX240AB01, the predicate device.

## 10. Conclusion as to Substantial Equivalence

The AURA DR43C-AG detector is substantially equivalent to the predicate device LLX240AB01 (K102587). Both subject and predicate devices are same or very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, their appearance, pixel pitch and weight are different. However the compliance reports, performance demonstrations in this submission STED provide demonstration that these differences do not raise any new questions of safety and effectiveness. Therefore, AbyzR CO., LTD. concludes the AURA DR43C-AG digital flat panel detector is substantially equivalent with the predicate device LLX240AB01 (K102587) of Samsung Mobile Display Co., Ltd.