August 25, 2021

ASTEL Inc.
% Mr. Dave Kim
President
Mtech Group
7505 Fannin St. Ste 610
HOUSTON TX 77054

Re: K212051
Trade/Device Name: RFA-1717DI (RFA-1717DIG, RFA-1717DIC)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 25, 2021
Received: June 30, 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)*
K212051

Device Name
RFA-1717DI
(RFA-1717DIG, RFA-1717DIC)

Indications for Use *(Describe)*
The RFA-1717DI 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."

ASTEL
ASICs & Systems for telecommunications

K212051

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 : August 23, 2021

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

Submitter's Name :	ASTEL Inc.
Submitter's Address:	26-79, Gajeongbuk-ro, Yuseong-gu, Daejeon, 34113, Korea
Submitter's Telephone:	Tel:+82-42-360-2100
Contact person:	Mr. Yonghwan, Jeon / Director of DR Business Unit
Official Correspondent:	Dave Kim, MBA
Address:	Mtech Group 7505 Fannin St. Ste 610, Houston, TX 77054
Telephone:	713-467-2607
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:	RFA-1717DI
Model Name:	RFA-1717DIG, RFA-1717DIC
Regulation Name:	Digital Flat Panel X-ray Detector
Regulation Number:	21 CFR 892.1680
Regulatory Class:	II
Product Code:	MQB
Predicate Device	
Device Name:	LLX240AB01(K102587) / LTX240AA01 (K090742)
Regulation Name:	Digital Flat Panel X-ray Detector
Regulation Number:	21 CFR 892.1680
Regulatory Class:	II
Product Code:	MQB

2. Device Description

The RFA-1717DI detector is a digital X-ray flat panel detector which has 43cm x 43cm imaging area and communicates with a wired communication feature, Giga-bit Ethernet communication method through connection of tether cable. The RFA-1717 detector is available in two types of scintillator: Csl: Tl type for RFA-1717DIC model and Gadox:Tb type for RFA-1717DIG model. The device accepts x-ray photons and the scintillator and emits visible spectrum photons that illuminate an array of photo (IGZO)-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 and imaging data management on network.

3. Indications for Use

The RFA-1717DI 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 RFA-1717DI 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 devices:

The RFA-1717DI detector described in this 510(k) have similar indications for use and technical characteristics as the predicate devices, LLX240AB01 (K102587) and LTX240AA01 (K090742) digital flat panel X-ray detector manufactured by Samsung Mobile Display Co., Ltd.

6. Substantial Equivalence

The RFA-1717DI detector and components conform to the FDA recognized standards. Based on the recognized standard conformity evidences related to electro-, mechanical-, software-, clinical-, and risk management, it is confirmed that The RFA-1717DI detector is substantially equivalent to the predicate devices.

Characteristic	ASTEL Inc. RFA-1717DI	Samsung Mobile Display LTX240AA01 / LLX240AB01	Remark
510(k) number	K212501	K090742 / K102587	
Intended Use	The RFA-1717DI 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.	LTX240AA01 Digital Flat Panel X-ray 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 systems in all general purpose diagnostic procedures. 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	Same

		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.	
Detector Type	IGZO, TFT	Amorphous Silicon, TFT	Similar
Scintillator	RFA-1717DIC: Cesium Iodide: TI RFA-1717DIG: Gadox : Tb	LTX240AA01: CsI LLX240AB01:GdOS	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	140µm	143µm	Similar
Resolution	3.4 lp/mm	3.5 lp/mm	Similar
MTF	79% at 0.5lp/mm (GdOS) 83% at 0.5lp/mm (CsI)	76% at 0.5lp/mm (GdOS) 81% at 0.5lp/mm (CsI)	Similar
DQE	34% at 1lp/mm (GdOS) 60% at 1lp/mm (CsI)	32% at 1lp/mm (GdOS) 50% at 1lp/mm (CsI)	
A/D conversion	16 bit	14 bit	Similar
Grayscale	65350 (16bit)	16384 (14bit)	Same
Data output	RAW *The RAW files are convertible into DICOM 3.0 by console S/W	RAW *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	Similar
Application	General Radiology system Available with upright stand, table, universal stand	General Radiology system Available with upright stand, table, universal stand	Same
picture			Similar

When compared to LLX240AB01 (K102587) and LTX240AA01 (K090742), the RFA-1717DI presented in this submission has the same characteristics in:

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

There is no significant difference between the RFA-1717DI and the predicate devices that would adversely affect the use of the product. Both devices are substantially equivalent in terms of design, function, materials, operational principles and intended use.

7. Performance Testing/Data

Results for verification and validation testing of the subject device was found acceptable to support the claims of substantial equivalence. Electrical safety and EMC compliance were tested according to the IEC Standards. ASTEL Inc. certifies conformance to Voluntary Standards covering electrical, mechanical safety and EMC compliance. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate devices in terms of safety and effectiveness.

8. Description of non-clinical tests.

- Non-clinical study

The non-clinical performance testing of the subject device confirms that the performance values in comparison of DQE, MTF NPS are basically equivalent to the predicate devices, LLX240AB01 (K102587) and LTX240AA01 (K090742).

The non-clinical test report the subject device was prepared and submitted to FDA to demonstrate the substantial equivalency of the subject devices compared to each respective predicate devices. The non-clinical test report contains the MTF and DQE performance results of RFA-1717DI in accordance with IEC 62220-1 standard. The comparative result of the MTF test for RFA-1717DI detector demonstrated that the MTF of RFA-1717DI performed similarly compare to the predicate devices. The DQE represents the ability to visualize object details of a certain size and contrast. RFA-1717DI demonstrated higher DQE performance than LLX240AB01 and LTX240AA01 at all spatial frequencies of both detectors.

-Electrical safety and EMC

RFA-1717DI has been tested for electrical safety standard IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 *2007) + AM1 (2012) and electromagnetic compatibility IEC 60601-1-2: 2014, CISPR 11: 2015 Group 1, Class A, IEC61000-3-2: 2014, IEC 61000-3-3: 2013, EN 55011: 2009 +A1: 2010, EN 60601-1-2:2015, EN 61000-3-2:2014, EN 61000-3-3:2013.

The software validation and verification testing was also performed. The results of nonclinical testing indicate that the RFA-1717DI detector is as safe and effective as the predicate devices.

Compliance evidences were submitted for the following standards:

- IEC 60601-1: 2005, MOD Test Report issued by 3rd party testing lab
- IEC 60601-1-2: 2014, Test Report issued by 3rd party testing lab
- ISO 14971: Risk management file
- Non-clinical consideration according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices"
- "Guidance for the Contents of Premarket Submission for Software Contained in Medical Device".

9. Description of clinical tests.

No clinical testing is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. Bench testing is sufficient to assess the device safety and effectiveness, including demonstrating equivalent image quality.
Sample clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device but they provide further evidence in addition to the laboratory performance data to show that the subject device operates as indicated.

10. Conclusion as to Substantial Equivalence

The RFA-1717DI detector is substantially equivalent to the predicate devices LLX240AB01 (K102587) and LTX240AA01 (KJ090742). Both the 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, appearance, pixel pitch and weight are different. However, the compliance reports, performance testing and clinical image review result in this submission STED demonstrate that these differences do not raise any new questions of safety and effectiveness. Therefore, ASTEL Inc. concludes the RFA-1717DI digital flat panel detector is substantially equivalent with the predicate devices LLX240AB01 (K102587) and LTX240AA01 (K090742) of Samsung Mobile Display Co., Ltd.