Bontech Co. Ltd.
℅ Mr. Dave Kim
President
Mtech Group
7707 Fannin Street, Suite 200
HOUSTON TX 77054

April 23, 2020

Re: K200787
Trade/Device Name: BSD3543W
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: March 24, 2020
Received: March 26, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200787

Device Name
BSD3543W

Indications for Use *(Describe)*

The BSD3543W (BT-DA22W/BT-DB22W) 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.

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510(k) Summary
K200787

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

Date of Submission April 17, 2020

I. SUBMITTER

Submitter's Name	BONTECH Co., Ltd.
Submitter's Address	Youngtong-gu Youngtong-dong 980-3, Digital Empire D #1201, Suwon city, Gyeonggi-do, South Korea 443-702
Submitter's Telephone	+82 (31) 303-5254
Contact person	Mr. Ki Chan Ahn / RA Manager
Official Correspondent	Dave Kim (davekim@mtech-inc.net)
Address	7707 Fannin St. Ste 200, Houston, TX 77054
Telephone	+713-467-2607

II. DEVICE

Trade/proprietary Name	BSD3543W Digital Flat Panel X-ray Detector
Model No.	BT-DA22W / BT-DB22W
Common or Usual Name	Solid State X-ray Imager (Flat Panel/Digital Imager)
Regulation Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680
Product Code	MQB
Regulatory Class	Class II
Over the Counter Use	

III. PREDICATE DEVICE

Primary Manufacturer	BONTECH Inc.
Device Name	BSD3543 Digital Flat Panel X-ray Detector
510(k) Number	K162487
Regulation Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680 (Product Code: MQB)
Regulatory Class	Class II

IV. REFERENCE DEVICE

Trade/Device Name:	ClearVision Exam Vue Flat Panel Detector
510(K) Number	K160143
Regulation Name:	stationary X-ray System
Regulation Number	21 CFR 892.1680 (Product Code: MQB)
Regulatory Class	Class II

V. DEVICE DESCRIPTION

BSD3543W (BT-DA22W/BT-DB22W) is a digital X-ray flat panel detector which intercepts x-ray photons and the scintillator (BT-DB22W(Gdos) / BT-DA22W(CsI)) 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. The BSD3543W is a wireless version of the predicate device, the BSD3543.

VI. INDICATIONS FOR USE:

The BSD3543W (BT-DA22W/BT-DB22W) 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.

VII. PREDICATE COMPARISON

Characteristic	Proposed BONTECH BSD3543W (BT-DA22W/BT-DB22W)	Predicate BONTECH BSD3543 (BT-DA22-IA/BT-DB22-IA)	Remark
510(k) number	K200787	K162487	

Indications for Use	The BSD3543W (BT-DA22W/BT-DB22W) 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.				The BSD3543(BT-DA22-IA/BT-DB22-IA) 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.				Same
Detector Type	Amorphous Silicon (a-Si), TFT				Amorphous Silicon (a-Si), TFT				Same
Scintillator	BT-DB22W(Gdos) / BT-DA22W(CsI)				BT-DB22-IA(Gdos) / BT-DA22-IA(CsI)				Same
Imaging Area	14 x 17 inches				14 x 17 inches				Same
Pixel matrix	2500 x 3052				2500 x 3052				Same
Pixel pitch	140 μm				140 μm				Same
Resolution	3.5 lp/mm				3.5 lp/mm				Same
A/D conversion	16 bit				16 bit				Same
Grayscale	65,536 (16bit)				65,536 (16bit)				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
Viewing SW	Raw Image Viewer				Raw Image Viewer				Same
Dimensions	384 x 460 x 15 mm				350 x 428 x 15 mm				Similar
MTF (Spatial Resolution)	GDOS		CsI		GDOS		CsI		Similar
	%@1 lp.mm	60	%@1 lp.mm	60	%@1 lp.mm	59	%@1 lp.mm	58	

	%@2 lp.mm	29	%@2 lp.mm	28.2	%@2 lp.mm	28	%@2 lp.mm	26	
	%@3.5 lp.mm	12	%@3.5 lp.mm	10.6	%@3.5 lp.mm	10	%@3.5 lp.mm	10.	
DQE	GDOS		CsI		GDOS		CsI		Similar
	%@0 lp.mm	39.2	%@0 .lp.mm	70.1	%@0 lp.mm	39.2	%@0 lp.mm	68	
	%@1 lp.mm	30.2	%@1 lp.mm	60.2	%@1 lp.mm	29	%@1 lp.mm	57	
	%@2 lp.mm	24.9	%@2 lp.mm	54.5	%@2 lp.mm	24	%@2 lp.mm	51	
	%@3.5 lp.mm	14.7	%@3.5 lp.mm	29.7	%@3.5 lp.mm	14	%@3.5 lp.mm	27	
Power Supply	Input: 100~240 V, 50/60 Hz, Output: 12 V, 3.75 A				Input: 100~240 V, 50/60 Hz, Output: 12 V, 6 A				Same
Application	General Radiology system Available with upright stand, table, universal stand				General Radiology system Available with upright stand, table, universal stand				Same
picture									Similar
Wireless capability/ functionality	Proposed Device (K200787): Wireless, Wired				Predicate Device (K162487): Wired				
	The Clear Vision ExamVue Flat Panel Detector, the reference device (K160143), uses the same detector type, aSi TFTD. Both, the subject and reference devices are wired and wireless cassette sized panel with the same function and intended use. They offer the same size: 14x17 (35x43cm), and similar pixel size: 2500 x 3052 vs 2466 x 3040.								

When compared to the predicate device (K162487), the subject device, BSD3543W (BT-DA22W/BT-DB22W), presented in this submission has demonstrated equal or superior performances in terms of the following characteristics:

- Intended Use
- Pixel pitch
- Resolution
- MTF, DQE performance
- Operating principle
- Basic design
- Viewing software

The imaging area and pixel matrix of BSD3543W (BT-DA22W/BT-DB22W) and the predicate device are same. The subject device and the reference device are substantially equivalent in basic design, function, operational principles and intended use.

The Clear Vision ExamVue Flat Panel Detector, the reference device (K160143), uses the same detector type, aSi TFTD, for the collection of light generated by a CsI scintillator, for the purpose of creating a digital X-ray image.
The subject device and the reference device offer the same size, 14x17 (35x43cm), similar pixel size, 2500x 3052 vs 2466 x 3040, both wired and wireless cassette sized panel, function and intended use.

VIII. SUMMARY OF NON-CLINICAL TESTS

The following FDA guidance documents were used in the development of BSD3543W.

- "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"
- "Radio Frequency Wireless Technology in Medical Devices"

To minimize electrical and mechanical hazards, BONTECH adheres to recognized and established industry practice, and all equipment complies with the relevant FDA and international standards.

Through verification and validation activities, 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.:

Electrical Safety:
Testing was conducted in accordance with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2012 reprint))

Electromagnetic Compatibility:
Testing was conducted in accordance with IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for basic safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software:
The viewing software for the subject device is identical to the predicate device. Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005)

Performance testing was conducted to show that the subject device performs as intended and equally or superior than the performance of the predicate device.

The non-clinical performance testing constrains that the main physical values for performance of X-ray detectors such as DQE and MTF. The performance test results show that the subject device, BSD3543W (BT-DA22W/BT-DB22W), offers almost identical but superior imaging performance compared to BSD3543 at all spatial frequencies. The ability of BSD3543W (BT-DA22W/BT-DB22W) to utilize the input image signal are similar to BSD3543 at same patient exposure levels as shown in the detective quantum efficiency graph.

The detector is tested for the integration to a generator and viewing software as below.
-Generator:

- kV Range: 40~125kV, 1kV step (Optional 40~150kV)
- mA Range: 10 to 500mA
- Timer Range: 0.001 to 10 sec, 38 steps

-Viewing Software:
S/W name: Raw Image Viewer, Version: 1.1

- Data format: raw

The subject device's wireless transmission parameters were evaluated using E.U.T for radio frequency wireless coexistence test. These parameters are used to assess the quality of service (QoS) provided by the subject device wireless function.
To characterize the wireless medical telemetry system for this QoS study, the measured parameters consisted of 1) Image acquired, 2) Receiving signal level, 3) delay time, 4)Through, and 5) signal strength and the outcomes passed the pre-defined acceptance criteria of quality of service (QoS) by the subject device.

IX. SUMMARY OF CLINICAL TESTS

Images taken from the predicate and subject devices were reviewed and rated in comparison by an American board-certified radiologist.
Based on image comparison test and data analysis, images taken from BSD3543W, the subject device, have similar quality overall compared with BSD3543, the predicate device. There are no other radiographic abnormalities and any issue with diagnostic images.

X. CONCLUSIONS

Based on the information above, BSD3543W (BT-DA22W/BT-DB22W) digital flat panel detector is substantially equivalent to the predicate device.