



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Bontech Inc.  
% Mr. Dave Kim  
Medical Device Regulatory Affairs  
Mtech Group  
8310 Buffalo Speedway  
HOUSTON TX 77025

October 14, 2016

Re: K162487  
Trade/Device Name: BSD3543 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: September 2, 2016  
Received: September 7, 2016

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

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

## Indications for Use

510(k) Number (if known)

K162487

Device Name

BSD3543 Digital Flat Panel X-ray Detector

Indications for Use (Describe)

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.

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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## 510(k) Summary

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

Date of Submission September 2, 2016

### I. SUBMITTER

Submitter's Name	BONTECH Inc.
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
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Address	8310 Buffalo Speedway, Houston, TX 77025
Telephone	+713-467-2607
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### II. DEVICE

Trade/proprietary Name	BSD3543
Model No.	Digital Flat Panel X-ray Detector
Common or Usual Name	BT-DA22-IA / BT-DB22-IA
Regulation Name	Solid State X-ray Imager (Flat Panel/Digital Imager)
Regulation Number	Stationary X-ray System
Product Code	21 CFR 892.1680
Regulatory Class	MQB
Over the Counter Use	Class II

### III. PREDICATE DEVICE

Primary Manufacturer	BONTECH Inc.
Device Name	BSD3543
510(k) Number	Digital Flat Panel X-ray Detector
Regulation Name	K160204
Regulation Number	Stationary X-ray System
Regulatory Class	21 CFR 892.1680 (Product Code: MQB)
	Class II

#### IV. DEVICE DESCRIPTION

BSD3543(BT-DA22-IA/BT-DB22-IA) is a digital X-ray flat panel detector which intercepts x-ray photons and the scintillator (BT-DB22-IA(Gdos) / BT-DA22-IA(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.

#### V. INDICATIONS FOR USE:

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.

#### VI. PREDICATE COMPARISON

<b>Characteristic</b>	Proposed BONTECH BSD3543 (BT-DA22-IA/BT-DB22-IA)	Predicate BONTECH BSD4343	Remark
<b>510(k) number</b>	-K162487	K160204	
<b>Indications for Use</b>	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.	The BSD4343 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
<b>Detector Type</b>	Amorphous Silicon, TFT	Amorphous Silicon, TFT	Same

<b>Scintillator</b>	BT-DB22-IA(Gdos) / BT-DA22-IA(CsI)				Gadolinium Oxysulfide (Gdos)		Similar
<b>Imaging Area</b>	14 x 17 inches				17 x 17 inches		Similar
<b>Pixel matrix</b>	2500 x 3052				3072 x 3072		Similar
<b>Pixel pitch</b>	140 μm				140 μm		Same
<b>Resolution</b>	3.5 lp/mm				3.5 lp/mm		Same
<b>A/D conversion</b>	16 bit				16 bit		Same
<b>Grayscale</b>	65,536 (16bit)				16384 (14bit)		Similar
<b>Data output</b>	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
<b>Viewing SW</b>	Raw Image Viewer				Raw Image Viewer		Same
<b>Dimensions</b>	384 x 460 x 15 mm				460 x 460 x 15 mm		Similar
<b>MTF (Spatial Resolution)</b>	GDOS		CsI		GDOS		Similar
	%@1 lp.mm	58.7	%@1 lp.mm	60	%@1 lp.mm	52.3	
	%@2 lp.mm	27.2	%@2 lp.mm	28.1	%@2 lp.mm	23	
	%@3.5 lp.mm	11.2	%@3.5 lp.mm	12.4	%@3.5 lp.mm	10	
<b>DQE</b>	GDOS		CsI		GDOS		Similar
	%@0 lp.mm	37.9	%@0 .lp.mm	70	%@0 lp.mm	39.1	
	%@1 lp.mm	29.7	%@1 lp.mm	59.4	%@1 lp.mm	24.7	

	% @2 lp.mm	22.4	% @2 lp.mm	51.4	% @2 lp.mm	16.3	
	% @3.5 lp.mm	10.8	% @3.5 lp.mm	28	% @3.5 lp.mm	10	
<b>Power Supply</b>	Input: 100~240 V, 50/60 Hz, Output: 12 V, 6 A				Input: 100~240 V, 50/60 Hz, Output: 12 V, 6 A		Same
<b>Application</b>	General Radiology system Available with upright stand, table, universal stand				General Radiology system Available with upright stand, table, universal stand		Same
<b>picture</b>							Similar

When compared to the predicate device (K160204), the BSD3543(BT-DA22-IA/BT-DB22-IA) presented in this submission has the same characteristics in the following:

- Intended Use
- Pixel pitch
- Resolution
- Operating principle
- Basic design
- Viewing software

The imaging area and pixel matrix of BSD3543(BT-DA22-IA/BT-DB22-IA) and the predicate device are different but they would not adversely affect the use of the product. Both devices are substantially equivalent in basic design, function, operational principles and intended use.

## VII. SUMMARY OF NON-CLINICAL TESTS

The bench testing performed to compare the subject devices to the predicate followed FDA’s guidance document: “Guidance for the Submission of 510(k)s for Solid State X-ray Imaging 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. For example, electrical, mechanical, environmental safety and

performance testing according to standard EN60601-1:2006+A1:2013 or IEC60601-1:2005 3.0 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, 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 AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

#### Electromagnetic Compatibility:

Testing was conducted in accordance with IEC 60601-1-2:2007 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 better than the performance of the predicate device.

The non-clinical performance testing constrains that the main physical values for comparison of X-ray devices like DQE and MTF are basically equivalent to the predicate device BSD4343 (K160204). The results show that BSD3543(BT-DA22-IA/BT-DB22-IA) offer similar or better resolution performance than BSD4343 at 0 ~ 3.5lp/mm spatial frequencies. Moreover, the ability of BSD3543(BT-DA22-IA/BT-DB22-IA) to utilize the input image signal are more efficient than BSD4343 at same patient exposure as shown in the detective quantum efficiency graph.

These tests were conducted under conditions of single and double pumping mode and for the varying power sources (e.g., AC/DC power vs. battery power).

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

## **VIII. SUMMARY OF CLINICAL TESTS**

Images reviewed were not necessary to establish substantial equivalence based on the modifications to the device as evidenced in the laboratory performance data to show that the subject device operates as the indicated.

## **IX. CONCLUSIONS**

Based on the information above, BSD3543(BT-DA22-IA/BT-DB22-IA) digital flat panel detector is substantially equivalent to the predicate device.