Office of the Attorney General
Leonard M. Rapadas
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287 West O'Brien Drive
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Attorneys for the Government of Guam

BEFORE THE OFFICE OF PUBLIC ACCOUNTABILITY PROCUREMENT APPEAL

IN THE APPEAL OF JMI-EDISON	)	APPEAL No. OPA-PA-11-001
	)	
APPELLANT.	)	
	)	
	)	**CERTIFICATION OR EXEMPTION OF RADIOLOGY IMAGING SYSTEM**
	)	
	)	
	)	
	)	
	)	

Attached hereto is documentation relative to the certification of the Shimadzu RadSpeed DR-Auto Radiology Imaging System.

Based upon the attached information, the Shimadzu RadSpeed DR-Auto Radiology Imaging System is approved, or exempted from the approval process on a component by component basis pursuant to 21 USC §510(k), and 21 CFR §892, et seq. Attached, find the documentation to demonstrate either the certification of a device for use in interstate commerce.

or the exemption of the device from further certification. The following information, provided by Shimadzu Corporation and MedPharm, advises that the components of the RadSpeed DR-Auto Radiology Imaging System are FDA certified or exempt from certification. Exhibit A. Philip J. Manley, Gamma Corporation, Hawaii, who serves as a consultant to the Guam Memorial Hospital concerning radiological equipment, including x-ray devices similar to the one acquired in this matter, confirms that in the United States the FDA approval provided for here is the standard for the independent evaluation of safety and effectiveness. Exhibit B.

The Department of Public Health and Social Services finds that the Shimadzu RadSpeed DR-Auto Radiology Imaging System meets or exceeds the specifications published for this acquisition. The information provided verifies that the equipment meets Food and Drug Administration quality assurance, safety, and effectiveness requirements. This information is respectfully provided here.

Submitted this 5th day of December, 2011.

OFFICE OF THE ATTORNEY GENERAL
Leonard M. Rapadas, Attorney General

By: John Weisenberger
John Weisenberger
Assistant Attorney General

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	)	
	)	
	)	
	)	
	)	

Exhibit A

RadSpeed FDA Compliance

Shimadzu did not file the RadSpeed as a "System". Rather the RadSpeed was submitted by its components. Only certain components were required to go through the 510(k) process. Most components are considered exempt.

Below is a listing of most major components of the RadSpeed and their respective classifications and listings for the FDA. The Radspeed Combinations presently being offered are:

1. UD150B-40 Generator: Exempt
2. CH-200 Ceiling Tube Support: Exempt
3. BK-200 Bucky Table: Exempt
4. BR-120 Wall Bucky Stand: Exempt
5. R-30H Collimator See attached
6. 0.6/1.2P324DK-85(SF) Tube: Exempt
7. Canon CXDI-55C – See attached

SHIMADZU MEDICAL SYSTEMS		CDRH Initial Report	FDA 510(k)
System Type	Model Number	Accession Number	K Number
Radiographic System (RadSpeed)	UD150L-40	0412184-00	Exempt
	UD150V-40	0412174-00	Exempt
	UD150B-40	0410328-00	Exempt
	R20-J	0510140-00	K042840
	CH-200M	on R-20J-0510140-00	Exempt
	CH-200	on R-30H-0412393-00	Exempt
	BK-200	0412396-00	Exempt
	BK-200F	0512081-00	Exempt
	BR-120	0412394-00	Exempt
	BR-120F	0512082-00	Exempt
	BR-120FT	0512079-00	Exempt
	DAR-7000	0512277-00	K050925
	R-30H	0412393-00	K031771
X-ray tube	0.3/0.8P323DK-85	0610180-00	Exempt
	0.6/1.2P324DK-125(SF)	0411680-00	Exempt
	0.6/1.2P364DK-125(SF)	0411678-00	Exempt
	0.6/1.2P364DK-85(SF)	0411677-00	Exempt
	0.6/1.2P324DK-85(SF)	0411681-00	Exempt
	0.6/1.2P38DE-85(SF)	0411684-00	Exempt

You may access the regulations by the following link:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

CFR - Code of Federal Regulations Title 21

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

Diagnostic x-ray high voltage generator.

The device is exempt from the premarket notification procedures

CFR - Code of Federal Regulations Title 21

New Search

Help | More About 21CFR

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

Diagnostic x-ray tube mount.

... diagnostic x-ray tube mount is a ... and to position the diagnostic ... for a medical radiographic ...

... The device is exempt ... pre...cket notification procedures ...

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 20..]
[CITE: 21CFR892.1490]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892--RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1490 Radiologic table.

(a) *Identification.* A [illegible] intended for medical purposes to support [illegible] radiologic procedures. [illegible] and may be [illegible].

(b) *Classification.* [illegible]. The device is exempt from the premarket notification procedures

SHIMADZU

SHIMADZU PHILIPPINES CORPORATION

[illegible]

CEBU
[illegible]

DAVAO
[illegible]

SHIMADZU

CERTIFICATION

This is to certify that Shimadzu Radspeed DR Auto X-Ray machine with the following items:

*1.) **X-Ray High Voltage Generator***
Model: UD150B-40
Serial no.: 3M5249A14001

Includes item #:
***10**. Starter, Model: SA-42UD*
Serial no.: 3M5566814010
as one of its components.

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2011]
[CITE: 21CFR892.1700]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892 -- [illegible]

Subpart B--Diagnostic Devices

Sec. 892.1700 Diagnostic x-ray high voltage generator.

(a) Identification. A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the x-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.

(b) Classification. Class [illegible] (general controls). The device is exempt from the premarket notification procedures in subpart [illegible] of this chapter, subject to the limitations in 892.9.

[illegible] FR [illegible], Jan. 20, 1988, as amended at [illegible] FR [illegible], Jan. [illegible]; [illegible] FR [illegible], July 28, 2011]

- ***Source:***
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=892.1700

2.) *Diagnostic X-Ray Tube Mount (Ceiling Support)*
Model: CH-200
Serial no.: 3ZC5C2714001

Includes Items #:
11. *Auto positioning Assy*
Serial no.: 40D185A13004
12. *Arm SID Assy*
Serial no.: 3ZE8D011201E
13. *Motor Drive Unit*
Serial no.: 40D6DE414001
14. *Updown Synchro Assy*
Serial no.: 3ZCA45414005
are part of its components.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

- ***Source:***
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=892.1770

*3.) **Radiologic Table (Bucky Table)***
Model: BK-200
Serial no.: 402AB9E14001

Includes items #:
7. FPD Mount Kit, BK
Serial no.: 415534B14002
8. SPT-XD-F1A
Serial no.: 3M3319614003
are part of its components.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

- *Source:*
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=892.1980

4.) Collimator
Model: R-300
Serial no.: MP0271312008

Includes item #:
9. *Dosimeter (VAC) Assy*
Serial no.: MP03C8D14003
as one of its components.

- *501(K) Number: K101039*
- *501(K) certificate on separate sheet*
- *Source: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K101039.pdf*

5.) Wall-mounted Radiographic Cassette Holder (Vertical Bucky)
Model: BR-120T
Serial no.: 40B4AAB14001

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

- *Source:*
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.../m?fr=892.1880

6.) ***Diagnostic X-ray Tube Housing Assembly (X-ray Tube)***
Model: 0.6/1 2P324DK-85
Serial no.: CM6D85815012

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2011]
[CITE: 21CFR892.1760]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 892--RADIOLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 892.1760 Diagnostic x-ray tube housing assembly.

(a) *Identification.* A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers and other appropriate components.

(b) *Classification.* Class II (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 892.9.

[53 FR 1961, Jan. 26, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38418, July 24, 2001]

- *Source:*
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=892.1760

Certified by:

SHIMADZU PHILIPPINES CORP.

ANTHONY PIMENTEL
Senior Service Manager

K091436

Section 10: Summary

MAY 29 2009

510(k) Summary

Prepared: April 6, 2009

Submitter:

Company Name:	Canon USA, Inc. (U.S. agent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Ms. Sheila Driscoll
Phone Number:	(516) 328-5602
Fax Number:	(516) 328-5169

Proposed Device:

Reason for 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-55C
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-50C
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K060433

Description of Device:

The DIGITAL RADIOGRAPHY CXDI-55C is a solid state x-ray imager which has 35 x 43 cm imaging area.

The DIGITAL RADIOGRAPHY CXDI-55C intercepts x-ray photons and the scintillator of the CXDI-55C emits visible spectrum photons that illuminate an array of photo-detectors that create electrical signals. After the electrical signals are generated, the images are converted to digital and displayed on a monitor.

Intended Use:

The DIGITAL RADIOGRAPHY CXDI-55C provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

This device is not intended for mammography applications.

K091436

Section 10: Summary

Comparison to Predicate:

CXDI-55C's intended use is the same as that of CXDI-50C. The differences are the external dimensions and the weight which are:

The external dimensions of CXDI-55C are changed from 491 x 477 x 23 mm to 480 x 481 x 15 mm.

The weight of CXDI-55C is changed from 4.8kg to 3.4kg.

Conclusion:

The Performance Data demonstrates that CXDI-55C is safe and effective just as the CXDI-50C.

Based on the information in this submission, similarity to the predicate device (Digital Radiography CXDI-50C), and the results of our design control activities and non-clinical testing, it is the opinion of Canon Inc. that the DIGITAL RADIOGRAPHY CXDI-55C described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2009

Canon USA, Inc.
% Mr. Jeff D. Rongero
Third Party Reviewer-Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratories Drive
Triangle Park, NC 27709

Re: K091436
Trade/Device Name: CXDI-55C
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: MQB
Dated: May 13, 2009
Received: May 14, 2009

Dear Mr. Rongero:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(K)Number(if known): K091436

Device Name: CXDI-55C

Indications for Use:

DIGITAL RADIOGRAPHY CXDI-55C provides digital image capture for conventional film/screen radiographic examinations.
The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.
This device is not intended for mammography applications.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091436

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Shimadzu Corporation
% Mr. Don Karle
Director, National Service
Shimadzu Medical Systems USA
20101 South Vermont Avenue
TORRANCE CA 90502

NOV - 6 2009

Re: K090578
Trade/Device Name: R-30II
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZW and IZX
Dated: September 8, 2009
Received: October 7, 2009

Dear Mr. Karle:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION XII : INTENDED USE

510(K) Number(if known) : Unknown K090578

Device Name: R-30H

Intended Use :

The R-30H is used to take the radiography of patients.

The intended for use of the R-30H are also the same as of the predicate beam limiting device R-30H (K031771).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per21CFR801.109) L OR Over-The-Counter Use

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090578

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BEFORE THE OFFICE OF PUBLIC ACCOUNTABILITY
PROCUREMENT APPEAL

IN THE APPEAL OF JMI-EDISON APPELLANT.	) APPEAL No. OPA-PA-11-001)))) **CERTIFICATION OR EXEMPTION OF RADIOLOGY IMAGING SYSTEM**)))))

Exhibit B

-----Original Message-----
From: Philip J. Manly [mailto:Pjmanly@connectimaging.com]
Sent: Saturday, September 24, 2011 12:35 PM
To: Patrick Lujan
Cc: Garibaldi Famisaran
Subject: Re: Guam Public Health contact

Patrick,

When we talked, you showed me a ruling by a judge indicating he wanted you to have an independent evaluation done on the x-ray equipment that was installed at your clinic.

In the United States, all medical equipment must be approved by the Food and Drug Administration (FDA) for safety and effectiveness before being offered for sale. For medical equipment such as x-ray machines used for medical purposes, the manufacturer applied for and receives 510(k) approval from the FDA.

You indicated to me that this equipment has 510(k) approval for sale in the United States. Such approval should satisfy the ruling by the judge for an independent evaluation of the safety and effectiveness of the equipment. If necessary, you can obtain a copy of the approval through the vendor for the equipment and submit it as proof of the evaluation for safety and effectiveness.

Sincerely,

Philip J. Manly, M.S., CHP, DABR

>>> On 9/21/2011 at 3:14 PM, in message
<aeee467c-5718-48d2-b3c2-0338e1d2da1d@ggmail01.dmrpacific.com>, Patrick Lujan <patrick.lujan@dphss.guam.gov> wrote:

Hafa adai Doc,

This is Patrick. You can reply to this email address.

thanks!

--
PATRICK Q. LUJAN
PHEP Manager/Planner IV
(671)735-7307 (w)
(671) 898-7307 (c)
patrick.lujan@dphss.guam.gov