



Office of the Attorney General
Leonard M. Rapadas
 Attorney General of Guam
 Civil Division
 287 West O'Brien Drive
 Hagatña, Guam 96910 • USA
 (671) 475-3324 • (671) 472-2493 (Fax)
 www.guamattorneygeneral.com

Attorneys for the Government of Guam

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 OFFICE OF PUBLIC ACCOUNTABILITY
 PROCUREMENT APPEALS
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 FILE NO. OPA-PA-11-001

**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**
) **AMENDED**
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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.

COPY

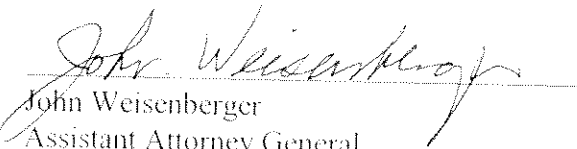
or the exemption of the device from further certification. The following information, provided by Shimadzu Corporation and MedPharm, advises that the components of the RadSpeed DR-Auto Radiology Imaging System are FDA certified or exempt from certification. Exhibit A, Philip J. Manley, Gamma Corporation, 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 and the General Services Agency find 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 12th day of December, 2011.

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

By:


John Weisenberger
Assistant Attorney General



Office of the Attorney General

Leonard M. Rapadas

Attorney General of Guam

Civil Division

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Attorneys for the Government of Guam

**BEFORE THE OFFICE OF PUBLIC ACCOUNTABILITY
PROCUREMENT APPEAL**

IN THE APPEAL OF JMI-EDISON

APPELLANT,

) APPEAL No. OPA-PA-11-001

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**CERTIFICATION OR EXEMPTION OF
RADIOLOGY IMAGING SYSTEM**

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	0412395-00	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	0.3/0.8P123DK-85	0610180-00	Exempt
	0.6/1.2P324DK-85(SF)	0411680-00	Exempt
	0.6/1.2P364DK-85(SF)	0411678-00	Exempt
	0.6/1.2P364DK-85(SF)	0411681-00	Exempt
	0.6/1.2P324DK-85(SF)	0411681-00	Exempt
	0.6/1.2P38DE-85(SF)	0411694-00	Exempt

You may access the regulations by the following link:

<http://www.accessdata.fda.gov/scripts/cdrh/cldocs/cfCFR/CFRSearch.cfm>

CFR - Code of Federal Regulations Title 21



[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation Products](#) | [X-Ray Assembler](#) | [Medical Reports](#) | [CLIA](#)

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Search for a device by:
Device Name
Device Model
Device Manufacturer
Device Classification



See Related Information

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

21 CFR 1010.10-10

Diagnostic x-ray high voltage generator.

(a) This section applies to diagnostic x-ray high voltage generators that are used to produce x-rays for diagnostic purposes. The device must be designed and constructed so that it will not produce x-rays of a higher energy than that specified in the labeling. The device must also be designed and constructed so that it will not produce x-rays of a higher intensity than that specified in the labeling. The device must also be designed and constructed so that it will not produce x-rays of a higher dose rate than that specified in the labeling. The device must also be designed and constructed so that it will not produce x-rays of a higher dose than that specified in the labeling.

(b) The device is exempt from the premarket notification procedures

CFR - Code of Federal Regulations Title 21

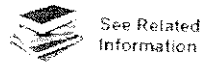


[510\(k\) | Adverse & Litigation | Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Regulations | Findings | X-Ray Assembler | Medsun Reports | CLIA](#)

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[Help | More About 21CFR](#)

21CFR 201.10.101-101.101.101
21CFR 201.10.101-101.101.101
21CFR 201.10.101-101.101.101
21CFR 201.10.101-101.101.101



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

21CFR 201.10.101-101.101.101

Diagnostic x-ray tube mount.

(a) This section applies to a diagnostic x-ray tube mount as a general use device under the jurisdiction of the Department of Health and Human Services, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health.

(b) This section does not apply to a diagnostic x-ray tube mount. The device is exempt from the premarket notification procedures of 21CFR 807.101.

CFR - Code of Federal Regulations Title 21



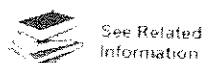
[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [Classification](#) | [Standards](#)

[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#)

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Code of Federal Regulations
(Title 21, Volume 8)
(Revised as of April 1, 2009)
(CFR: 21CFR892.1980)



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

Part 892--Radiologic table

Section 892.1980--

(a) Identification. A radiologic table is a device designed

for medical purposes to support a patient during radiologic procedures. The table may be fixed or portable and may be electrically powered.

(b) Classification. This device is Class II. The device is exempt from the premarket notification procedures

of part 801.401 of this chapter because the device is a

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 9]
[Revised as of April 1, 2011]
[CFR 21 CFR 892.17]

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

892.17

Medical X-Ray Diagnostic Equipment

Part 892.17--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 general type of device may include a transformer 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) Identification of applicable controls. The device is exempt from the premarket approval process provided it supports 21 CFR 892.17 and is marketed in compliance with 21 CFR 892.17.

21 CFR 892.17(a), (b) and (c) have been approved as 21 CFR 892.17(a), (b) and (c) by the FDA on 04/26/2011.

- **Source:**

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/cfCFRSearch.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.

Code of Federal Regulation
Title 21, Chapter I
Part 1770, Subpart A
Section 1770.1770

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

Part 1770, Subpart A
Section 1770.1770

Section 1770.1770

Section 1770.1770

Section 1770.1770

Section 1770.1770

• **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.

Code: Federal Acquisition Regulation
Title: 41 CFR 101-11.6
Revision as of April 12, 2011
Title: 41 CFR 101-11.6

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

1. Title of device
2. Model
3. Manufacturer
4. Date of approval

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

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- Source: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=892.1880>

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

Division of Federal Register
Title 21, Chapter I
Part 892.1760
21 CFR 892.1760

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

Part 892.1760

Chapter 892-Diagnostic devices


Part 892.1760 Diagnostic x-ray tube housing assembly

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

(B) Description of the device. The device is exempt from the premarket notification procedures in subpart E of part 892 of this title, subject to the limitations in 892.9.

(3) (1) (i) Date of issue and number: 61 FR 1175, Jan. 16, 1996; 61 FR 4913, July 27, 1996.

- **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

KC91436

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.

Section 10: Summary

Comparison to Predicate:

CXDI-55C's intended use is the same as that of CXDI-50C. 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 4.4kg.

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

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

MAY 29 2009

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.

Page 2

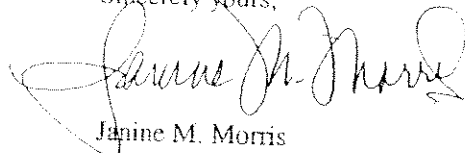
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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 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 ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Page 1 of 1

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Division of Health Service

Center for Drug Administration
10000 Hampshire Avenue
General Control Room - W006-0609
Silver Spring, MD 20993-0007

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-30H
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

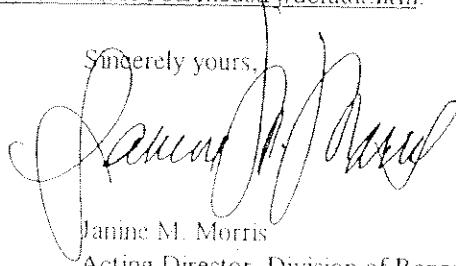
Page 2 -

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" (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 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

Page 1 of 1

510(K) Number (if known) Unknown K090578

Device Name: R-30H

Intended Use:

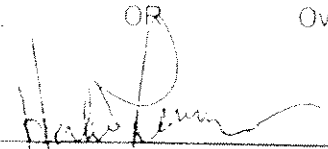
The R-30H is used to take the radiography of patients

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 OR Over-The-Counter Use
(Per 21CFR 801.109)



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



Office of the Attorney General
Leonard M. Rapadas
Attorney General of Guam
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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
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APPELLANT,)
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) CERTIFICATION OR EXEMPTION OF
) RADIOLOGY IMAGING SYSTEM
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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
<ae4ee467c-5718-48d2-b3c2-0338e1d2da1d@gmail01.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

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