DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

Form Approved: OMB Expiration Date: Dece See Reverse for OMB	mber 31, 2006	
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	OF A DIAGNOOTIO X-TV	4-2-4			
1. EQUIPMENT LOCATION		2. ASSEMBLER INFÖRMATION			
a. NAME OF HOSPITAL, DOCTOR OROFFICE WHERE INSTALLED		a. COMPANY NAME			
b. STREET ADDRESS		b. STREET ADDRESS			
c. CITY	d. STATE	c. CITY d. STATE			
e. ZIP CODE f. TELEPHONE NUMBER		e. ZIP CODE 1. TELEPHONE NUMBER			
, ,					
3. GENERAL INFORMATION a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH AF	RE (Check appropriate box(es))				
	are for corne allohe alterane monetanist	REASSEMBLY-MIXED SYSTEM (Both certified and non-certified components)			
NEW ASSEMBLY-FULLY CERTIFIED SYSTEM REASSEMBLY-FULLY CERTIFIED SYSTEM		REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM AN ADDITION TO AN EXISTING SYSTEM			
b. INTENDED USE(S) (Check appropriate (box(se))					
GENERAL PURPOSERADROGRAPHY GENERAL PURPOSEFLUOROSCOPY	UROLOGY MAMMOGRAPHY	CTWHOLE BODY SCANNER RADIATION THERAPY SIMULATOR HEAD-NECK (Medical) C-ARM FLUOROSCOPIC			
TOMOGRAPHY (Otherthen CT)	CHEST	DENTAL-INTRAORAL DIGITAL			
ANGIOGRAPHY	CHIROPRACTIC	DENTAL-CEPHALOMETRIC BONE MINERAL ANALYSIS			
PODIATRY	CT HEADSCANNER	DENTAL PANORAMIC OTHER (Specify in comments)			
c. THE X-RAY SYSTEM IS (Check one)	d. THE MASTER CONTROLIS IN	ROOM e. DATE OF ASSEMBLY			
STATIONARY					
MOBILE		(mm) (dd) (yyyy)			
4. COMPONENT INFORMATION (If additional with this Form Number, and complete Items		r this section use another form, replacing the preprinted number			
a. THE MASTER CONTROL IS b. CONTROL MANUFACTU	RER d	CONTROL SERIAL NUMBER 6. DATE MANUFACTURED			
A NEW INSTALLATION		4 AVERTALIANTI MALE (AT			
EXISTING (Certified) C. CONTROL MODEL NUM EXISTING (Non-certified)	SER	f. SYSTEM MODEL NAME (CT			
Complete the following information for the certified components listed		eam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicate			
spaces. For other certified components, enter in the appropriate block	s how many of each you install	d in this system.			
9. SELECTED COMPO		h. (Enter number of each inetailed in appropriate blocks.)			
MANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER	DATE MAN	JFACTURED X-RAY CONTROL CRADLE			
MANUFACTURER MODEL NUMBER	DATE MAN	JFACTURED HIGH VOLTAGE GENERATOR FILM CHANGER			
MANUFACTURER MODEL NUMBER	DATE MAN	JFACTURED VERTICAL CASSETTEHOLDER IMAGE INTENSIF			
MANUFACTURER MODEL NUMBER	DATE MAN	JFACTURED TUBE HOUSING ASSEMBLY SPOT FILM DEVI			
MANUFACTURER MODEL NUMBER	DATE MAN	JFACTURED DENTAL TUBE HEAD OTHER (Specify)			
		OTHER (already)			
5. ASSEMBLER CERTIFICATION					
the type required by the manufacturer(s), were of the type required by	the diagnostic x-ray performat If instruction manuals and othe	e, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were ce standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installer information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser he bottom of each copy.			
a. PRINTED NAME	b. SIGNATUR	E C. DATE			
6. COMMENTS		1			

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration Center for Devices and Radiological Health 1350 Piccard Drive (HFZ-240) Rockville, MD 20650 "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 control number."

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FORM FDA 2579 (12/03)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

Form Approved: OMB No. 0910-0025 Expiration Date: December 31, 2006 See Reverse for OMB statement

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1. EQUIPMENT LOCATION		2. ASSEMBLER INFORMATION			
a. NAME OF HOSPITAL, DOCTOR OROFFICE WHERE INSTALLED		a. COMPANY NAME			
b. STREET ADDRESS		b. STREET ADDRESS			
c. CITY d.	STATE	c. CITY d. STATE			
e. ZIP CODE f. TELEPHONE NUMBER		e. ZIP CODE f. TELEPHONE NUMBER			
()					
3. GENERAL INFORMATION					
a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Che	ock appropriate box(es))	REASSEMBLY-MIXED SYSTEM (Both cartified and non-certified components)			
NEW ASSEMBLY-FULLY CERTIFIED SYSTEM		REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM			
D. INTENDED USE(S) (Check appropriate (box(es))		AN ADDITION TO AN EXISTING SYSTEM			
GENERAL PURPOSE RADIOGRAPHY	UROLOGY	CT WHOLE BODY SCANNER RADIATION THERAPY SIMULATOR			
GENERAL PURPOSEFLUOROSCOPY	MAMMOGRAPHY	HEAD-NECK (Medical) C-ARM FLUOROSCOPIC			
TOMOGRAPHY (Otherthan CT)	CHEST	DENTAL-INTRAORAL DIGITAL			
ANGIOGRAPHY L	CHIROPRACTIC CT HEADSCANNER	DENTAL-CEPHALOMETRIC BONE MINERAL ANALYSIS DENTAL PANORAMIC OTHER (Specify in comments)			
	THE MASTER CONTROLIS IN				
STATIONARY					
MOBILE		(mm) (dd) (yyyy)			
4. COMPONENT INFORMATION (If additional space is needed for this section use another form, replacing the preprinted number with this Form Number, and complete Items 1, 4, and 5 only)					
a. THE MASTER CONTROLIS b. CONTROL MANUFACTURER	d.	CONTROL SERIAL NUMBER 6. DATE MANUFACTURED			
A NEW INSTALLATION					
EXISTING (Certified) c. CONTROL MODEL NUMBER EXISTING (Nan-certified)	f. SYSTEM MODEL NAME (CT Systems Only)				
Complete the following information for the certified components listed below		earn limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated			
spaces. For other certified components, enter in the appropriate blocks how					
9. SELECTED COMPONENTS		h. OTHER CERTIFIED COMPONENTS (Enter number of each installed in appropriate blocks.)			
MANUFACTURER MODEL NUMBER	DATE MANU				
WELL NO. SO. SO. SO. SO. SO. SO. SO. SO. SO. S	DATE MANU	FACTURED X-RAY CONTROL CRADLE			
		HIGH VOLTAGE GENERATOR FILM CHANGER			
MANUFACTURER MODEL NUMBER	DATE MANU	FACTURED VERTICAL CASSETTEHOLDER IMAGE INTENSIFIER			
MANUFACTURER MODEL NUMBER	DATE MANU	TUBE HOUSING ASSEMBLY SPOT FILM DEVICE			
MANUFACTURER MODEL NUMBER	DATE MANU	DENTAL TUBE HEAD OTHER (Specify)			
5. ASSEMBLER CERTIFICATION					
I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been fumished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.					
a. PRINTED NAME	b. SIGNATURE	c. DATE			
6. COMMENTS					

AND DESCRIPTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

Form Approved: OMB No. 0910-0025. Expiration Date: December 31, 2006 See Reverse for OMB statement

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1. EQUIPMENT LOCATION	2. ASSEM	2. ASSEMBLER INFORMATION			
8. NAME OF HOSPITAL, DOCTOR OROFFICE WHERE INSTALLED	a. COMPANY NAM	a. COMPANY NAME			

b. STREET ADDRESS	b. STREET ADDRE	SSS			
c. CITY d. STATE	c. CITY	d. STATE			
9. ZIP CODE f. TELEPHONE NUMBER	e. ZIP CODE	f. TELEPHONE NUMBER			
3. GENERAL INFORMATION					
a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropri	iate box(es)) REASSE	MBLY-MIXED SYSTEM (Both certified and non-certified components)			
NEW ASSEMBLY-FULLY CERTIFIED SYSTEM	REPLAC	EMENT COMPONENTS IN AN EXISTING SYSTEM			
REASSEMBLY-FULLY CERTIFIED SYSTEM	AN ADDI	ITION TO AN EXISTING SYSTEM			
b. INTENDED USE(S) (Check appropriate (box(es))					
GENERAL PURPOSERADIOGRAPHY UROLOG		LE BODY SCANNER RADIATION THERAPY SIMULATOR			
		ECK (Medical) C-ARM FLUOROSCOPIC			
TOMOGRAPHY (Other than CT) CHEST ANGIOGRAPHY CHIROP		-INTRAORAL DIGITAL -CEPHALOMETRIC BONE MINERALANALYSIS			
		PANORAMIC OTHER (Specify in comments)			
	ER CONTROLIS IN ROOM	e. DATE OF ASSEMBLY			
STATIONARY	III OOMII WEDIN I WOM				
MOBILE		(mm) (dd) (yyyy)			
4. COMPONENT INFORMATION (If additional space is	pooded for this postion us	an another form, raplacing the proprieted number			
with this Form Number, and complete Items 1, 4, and	5 only)	e another form, replacing the preprinted number			
a. THE MASTER CONTROLIS b. CONTROL MANUFACTURER	d. CONTROL SERIAL NUM	BER e. DATE MANUFACTURED			
A NEW INSTALLATION					
EXISTING (Certified) C. CONTROL MODEL NUMBER 1. SYSTEM MODEL NAME (CT Systems Only)					
EXISTING (Non-certified)					
Complete the following information for the certified components listed below which yo spaces. For other certified components, enter in the appropriate blocks how many of		ables and CT gantries enter the manufacturer and Model number in the indicated			
g. SELECTED COMPONENTS		OTHER CERTIFIED COMPONENTS			
		h (Enter number of each installed in appropriate blocks.)			
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED				
9 US STATE OF STATE O	DATE MANUFACTURED	X-RAY CONTROL CRADLE			
		HIGH VOLTAGE GENERATOR FILM CHANGER			
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED				
8		VERTICAL CASSETTEHOLDER IMAGE INTENSIFIER			
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED	TUBE HOUSING ASSEMBLY SPOT FILM DEVICE			
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED				
5 8 MANUFACTOREN	DATE MANOFACTORED	DENTAL TUBE HEAD OTHER (Specify)			
5. ASSEMBLER CERTIFICATION					
I affirm that all certified components assembled or installed by me, for which this rep	ort is being made, were artiusted and t	tested by me according to the instructions provided by the manufacturer(s) were of			
the type required by the manufacturer(s), were of the type required by the diagnostic accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction may within 15 days from the date of assembly, each copy of this report will be distributed	x-ray performance standard (21 CFR F inuals and other information required t	Part 1020), were not modified to adversely affect performance, and were installed in by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and,			
a. PRINTED NAME .	b. SIGNATURE	c. DATE			
6. COMMENTS					

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY

Form Approved: OMB No. 0910-0925. Expiration Date: December 31, 2006 See Reverse for OMB statement

OF A DIAGNO	D 1254987			
1. EQUIPMENT LOCATION	2. ASSEMBLER INFORMATION			
a. NAME OF HOSPITAL, DOCTOR OROFFICE WHERE INSTALLED	a. COMPANY NAME			
b. STREET ADDRESS	b. STREET ADDRESS			
c. CITY d. STATE	c. CITY d. STATE			
e. ZIP CODE f. TELEPHONE NUMBER	e. ZIP CODE f. TELEPHONE NUMBER ()			
3. GENERAL INFORMATION				
a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropriate NEW ASSEMBLY-FULLY CERTIFIED SYSTEM REASSEMBLY-FULLY CERTIFIED SYSTEM	REASSEMBLY-MIXED SYSTEM (Both certified and non-certified components) REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM AN ADDITION TO AN EXISTING SYSTEM			
b. INTENDED USE(S) (Check appropriate (box(es)) GENERAL PURPOSERADIOGRAPHY GENERAL PURPOSEFLUOROSCOPY TOMOGRAPHY (Other than CT) ANGIOGRAPHY PODIATRY C. THEX-RAY SYSTEM IS (Check one) STATIONARY MOBILE UROLOGY MAMMOGR CHEST CHEST CHEST GENERAL PURPOSEFLUOROSCOPY MAMMOGR CHEST CHEST GENERAL PURPOSEFLUOROSCOPY MAMMOGR CHEST CHEST GENERAL PURPOSEFLUOROSCOPY MAMMOGR CHEST GENERAL PURPOSEFLUOROSCOPY GENERAL PURPOSEFLUOROSCOPY MAMMOGR CHEST GENERAL PURPOSEFLUOROSCOPY MAMMOGR GENERAL PURPOSEFLUOROSCOPY GENERAL PURPOSEFLUOROSCOPY MAMMOGR GENERAL PURPOSEFLUOROSCOPY GENERAL PURPOSEFLUOROSCOPY MAMMOGR GENERAL PURPOSEFLUOROSCOPY GENERAL P	DENTAL-INTRAORAL DIGITAL DENTAL-CEPHALOMETRIC BONE MINERALANALYSIS			
4. COMPONENT INFORMATION (If additional space is needed for this section use another form, replacing the preprinted number with this Form Number, and complete Items 1, 4, and 5 only)				
a. THE MASTER CONTROLIS A NEW INSTALLATION EXISTING (Certified) EXISTING (Non-certified) Complete the following information for the certified components listed below which you is	d. CONTROL SERIAL NUMBER e. DATE MANUFACTURED f. SYSTEM MODEL NAME (CT Systems Only) f. SYSTEM MODEL NAME (CT Systems Only)			
spaces. For other certified components, enter in the appropriate blocks how many of ea	nstalled. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated ch you installed in this system.			
g. SELECTED COMPONENTS	h. CTHER CERTIFIED COMPONENTS (Enter number of each installed in appropriate blocks.)			
MANUFACTURER MODEL NUMBER WANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER	DATE MANUFACTURED X-RAY CONTROL CRADLE DATE MANUFACTURED			
MANUFACTURER MODEL NUMBER	HIGH VOLTAGE GENERATOR FILM CHANGER DATE MANUFACTURED			
MANUFACTURER MODEL NUMBER	VERTICAL CASSETTEHOLDER IMAGE INTENSIFIER DATE MANUFACTURED TUBE HOUSINGASSEMBLY SPOT FILM DEVICE			
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED DENTAL TUBE HEAD OTHER (Specify)			
5. ASSEMBLER CERTIFICATION				
I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.				
a. PRINTED NAME	b. SIGNATURE c. DATE			

6. COMMENTS