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

Form Approved: OME Expiration Date: Dece See Reverse for OME	mber 31, 2006	
Gas Levelse in Own	SIGNATION T	
В	105/007	4

	OF A DIAGROSTIC ATT				
1. EQUIPMENT LOCATION		2. ASSEMBLER INFORMATION			
a. NAME OF HOSPITAL, DOCTOR OR OFFICE 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	F /Chark annonnista hrw/se))				
	are fine carees adolors abras men provid moth	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(ee))					
GENERAL PURPOSE RADROGRAPHY GENERAL PURPOSE FLUOROSCOPY	UROLOGY MAMMOGRAPHY	CT WHOLE BODY SCANNER RADIATION THERAPY SIMULATOR HEAD-NECK (Modical) C-ARM FLUOROSCOPIC			
TOMOGRAPHY (Otherthen CT)	CHEST	DENTAL-INTRAORAL DIGITAL			
ANGIOGRAPHY	CHIROPRACTIC	DENTAL-CEPHALOMETRIC BONE MINERALANALYSIS			
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 o. DATE MANUFACTURED			
A NEW INSTALLATION EXISTING (Carified) C. CONTROL MODEL NUM	250	f. SYSTEM MODEL NAME (CT			
EXISTING (Non-certified)	dull	I. STOLEN MODEL INNIE (4)			
Complete the following information for the certified components listed spaces. For other certified components, enter in the appropriate block		seam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated			
g. SELECTED COMPO		h. (Enter number of each installed in appropriate blocks.)			
MANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER	DATEMAN	JFACTURED X-RAY CONTROL CRADLE			
MANUFACTURER MODEL NUMBER	DATE MAN	UFACTURED HIGH VOLTAGE GENERATOR FILM CHANGER			
MANUFACTURER MODEL NUMBER	DATE MAN	UFACTURED VERTICAL CASSETTE HOLDER IMAGE INTENSIFIE			
MANUFACTURER MODEL NUMBER	DATE MAN	UFACTURED TUBE HOUSINGASSEMBLY SPOT FILM DEVICE			
MANUFACTURER MODEL NUMBER	DATE MAN	UFACTURED DENTAL TUBE HEAD OTHER (Specify)			
MANUFACTURER MODEL NUMBER		Unich (openy)			
5. ASSEMBLER CERTIFICATION					
the type required by the manufacturer(s), were of the type required by	the diagnostic x-ray performar If instruction manuals and othe	ie, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were coe standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed if information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser as the bottom of each copy.			
a. PRINTED NAME	b. SIGNATUR	E c. DATE			
6. COMMENTS					

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."

		Septim 1		
	Section because of			
			Sing to a series	
		c as reco		
		c as reco		
		c as reco		
		printed the particular control of		
		Part Court III		

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

12	5	49	8	7	
----	---	----	---	---	--

1. EQUIPMENT LOCATION	2. ASSEMBLER INFORMATION				
a. NAME OF HOSPITAL, DOCTOR OROPFICE WHERE INSTALLED	a. COMPANY NAME				
b. STREET ADDRESS	b. STREET ADDRESS				
c. CITY d. STA	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 as NEW ASSEMBLY-FULLY CERTIFIED SYSTEM REASSEMBLY-FULLY CERTIFIED SYSTEM	Propriate bas(es)) 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 (Otherthen CT) ANGIOGRAPHY PODIATRY CT	DLOGY CT WHOLE BODY SCANNER RADIATION THERAPY SIMULATOR MMOGRAPHY HEAD-NECK (Medicel) C-ARM FLUOROSCOPIC EST DENTAL-INTRAORAL DIGITAL IROPRACTIC DENTAL-GEPHALOMETRIC BONE MINERAL ANALYSIS HEADSCANNER DENTAL PANORAMIC OTHER (Specify in comments) MASTER CONTROLIS IN ROOM a. DATE OF ASSEMBLY (mm) (dd) (yyyy)				
	Powed .				
with this Form Number, and complete Items 1, 4, a	e.is needed for this section use another form, replacing the preprinted number —— and 5 only)				
a. THE MASTER CONTROLIS b. CONTROL MANUFACTURER	d. CONTROL SERIAL NUMBER 6. DATE MANUFACTURED				
A NEW INSTALLATION EXISTING (Certified) EXISTING (Nan-certified) C. CONTROL MODEL NUMBER	SYSTEM MODEL NAME (CT Systems Only)				
Complete the following information for the certified components listed below which spaces. For other certified components, enter in the appropriate blocks how man	h you installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated y of each you installed in this system.				
9. SELECTED COMPONENTS	h. OTHER CERTIFIED COMPONENTS h. (Enter number of each installed in appropriate blocks.)				
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED				
9 SU	DATE MANUFACTURED X-RAY CONTROL CRADLE				
	HIGH VOLTAGE GENERATOR FILM CHANGER				
MANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER	DATE MANUFACTURED VERTICAL CASSETTEHOLDER IMAGE INTENSIFIER				
MANUFACTURER MODEL NUMBER	DATE MANUFACTURED TUBE HOUSING ASSEMBLY 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 instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the instructions provided by the instruction provided by the manufacturer(s), were of the instructions p					
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

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	S		
c CITY d. STATE			e. CITY	d. STATE		
e. ZIP CODE f. TELEPHONE NUMBER			e. ZIP CODE	f. TELEPHONE NUMBER		
3. GENERAL INFORMATION				<u> </u>		
a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropriate box(es))			REASSEMB	BLY-MIXED SYSTEM (Both certified and non-certified components)		
NEW ASSEMBLY-FULLY CERTII	FIEDSYSTEM		H	IENT COMPONENTS IN AN EXISTING SYSTEM		
b. INTENDED USE(S) (Check appropriate (box(es))	EDSYSTEM		AN ADDITIO	ON TO AN EXISTING SYSTEM		
GENERAL PURPOSE RADIOGR	APHY UROLOG	gγ	CT WHOLE	BODY SCANNER RADIATION THERAPY SIMULATOR		
GENERAL PURPOSEFLUOROS	SCOPY MAMMO	GRAPHY	HEAD-NEC	K (Medical) C-ARM FLUOROSCOPIC		
TOMOGRAPHY (Otherthan CT)	CHEST		DENTAL-IN			
ANGIOGRAPHY	CHIROP	RACTIC DSCANNER	DENTAL-CE	ANORIAMIC BONE MINERAL ANALYSIS OTHER (Specify in comments)		
c. THE X-RAY SYSTEM IS (Check one)	d. THE MASTE			e. DATE OF ASSEMBLY		
STATIONARY	0. 1112.1147.011					
MOBILE				(mm) (dd) (yyyy)		
4. COMPONENT INFORMATIO	ON (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)				
	CONTROL MANUFACTURER		d. CONTROL SERIAL NUMBE	e. DATE MANUFACTURED		
A NEW INSTALLATION EXISTING (Certified) C.	CONTROL MODEL NUMBER			f. SYSTEM MODEL NAME (CT Systems Only)		
EXISTING (Non-certified)				,		
Complete the following information for the certific spaces. For other certified components, enter in				les and CT gantries enter the manufacturer and Model number in the indicated		
spaces. For other certified components, enter in	the appropriate blocks nowmany or	each you ms	alled in this system.			
g. SELECTED COMPONENTS				h (Enter number of each installed in appropriate blocks.)		
MANUFACTURER	MODEL NUMBER	DATE M.	ANUFACTURED			
S EL MANUFACTURER MANUFACTURER	MODEL NUMBER DATE MAI		ANUFACTURED	X-RAY CONTROL CRADLE		
	DTW Made 19 VIVIMENT 9	NUMBER DATE MAI		HIGH VOLTAGE GENERATOR FILM CHANGER		
MANUFACTURER MODEL NUMBER DATE		DATE M.	ANUFACTURED			
8			VERTICAL CASSETTEHOLDER IMAGE INTENSIFIE			
MANUFACTURER MODEL NUMBER DATE		DATE M	ANUFACTURED	TUBE HOUSING ASSEMBLY SPOT FILM DEVICE		
MANUFACTURER	ACTURER MODEL NUMBER DATE N		ANUFACTURED			
G GA CT			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. SIGNAT		c. DATE		
			707 1 1	The second of th		
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 DIAGNOSTIC X-RAY SYSTEM 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			
6. ZIP CODE f. TELEPHONE NUMBER	ZIP CODE f. TELEPHONE NUMBER ()			
3. GENERAL INFORMATION				
a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropria 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			
	BRAPHY HEAD-NECK (Medical) C-ARM FLUOROSCOPIC DENTAL-INTRAORAL DIGITAL			
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. THEMASTER CONTROLIS A NEW INSTALLATION EXISTING (Cartified) EXISTING (Non-cartified) Complete the following information for the control of the contro	d. CONTROL SERIAL NUMBER e. DATE MANUFACTURED f. SYSTEM MODEL NAME (CT Systems Only) iii]!			
spaces. For other certified components, enter in the appropriate blocks howmany of e	installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated ach you installed in this system.			
g. SELECTED COMPONENTS	t. (Enter number of each installed in appropriate blocks.)			
MANUFACTURER MODEL NUMBER 8 8 8 8 MANUFACTURER MODEL NUMBER	DATE MANUFACTURED X-RAY CONTROL CRADLE CRADLE			
	HIGH VOLTAGE GENERATOR FILM CHANGER			
MANUFACTURER MODEL NUMBER MANUFACTURER MODEL NUMBER	DATE MANUFACTURED VERTICAL CASSETTEHOLDER IMAGE INTENSIFIER DATE MANUFACTURED TUBE HOUSING ASSEMBLY 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 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