

Form should NOT be submitted to FDA. See below for distribution list:  Distribution List:  State Radiation Health Office Purchaser Assembler	<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> <b>FOOD AND DRUG ADMINISTRATION</b> <b>REPORT OF ASSEMBLY</b> <b>OF A DIAGNOSTIC X-RAY SYSTEM</b>	Form Approved: OMB No. 0910-0025 Expiration Date: July 31, 2020 See Reverse for OMB statement Assembler/Purchaser Control Number
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### 1. EQUIPMENT LOCATION

a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED	
b. STREET ADDRESS	
c. CITY	d. STATE
e. ZIP CODE	f. TELEPHONE NUMBER (      )

### 2. ASSEMBLER INFORMATION

a. COMPANY NAME	
b. STREET ADDRESS	
c. CITY	d. STATE
e. ZIP CODE	f. TELEPHONE NUMBER (      )

### 3. GENERAL INFORMATION

a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropriate box(es))		<input type="checkbox"/> REASSEMBLY-MIXED SYSTEM (Both certified and non-certified components)
<input type="checkbox"/> NEW ASSEMBLY-FULLY CERTIFIED SYSTEM	<input type="checkbox"/> REASSEMBLY-FULLY CERTIFIED SYSTEM	<input type="checkbox"/> REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM
b. INTENDED USE(S) (Check appropriate (box(es)))		
<input type="checkbox"/> GENERAL PURPOSE RADIOGRAPHY	<input type="checkbox"/> UROLOGY	<input type="checkbox"/> CT WHOLE BODY SCANNER
<input type="checkbox"/> GENERAL PURPOSE FLUOROSCOPY	<input type="checkbox"/> MAMMOGRAPHY	<input type="checkbox"/> HEAD-NECK (Medical)
<input type="checkbox"/> TOMOGRAPHY (Other than CT)	<input type="checkbox"/> CHEST	<input type="checkbox"/> DENTAL-INTRAORAL
<input type="checkbox"/> ANGIOGRAPHY	<input type="checkbox"/> CHIROPRACTIC	<input type="checkbox"/> DENTAL-CEPHALOMETRIC
<input type="checkbox"/> PODIATRY	<input type="checkbox"/> CT HEADSCANNER	<input type="checkbox"/> DENTAL PANORAMIC
c. THE X-RAY SYSTEM IS (Check one)		<input type="checkbox"/> STATIONARY <input type="checkbox"/> MOBILE
d. THE MASTER CONTROL IS IN ROOM		e. DATE OF ASSEMBLY

### 4. COMPONENT INFORMATION

a. THE MASTER CONTROL IS <input type="checkbox"/> A NEW INSTALLATION <input type="checkbox"/> EXISTING (Certified) <input type="checkbox"/> EXISTING (Non-certified)	b. CONTROL MANUFACTURER	d. CONTROL SERIAL NUMBER	e. DATE MANUFACTURED
c. CONTROL MODEL NUMBER		f. SYSTEM MODEL NAME (CT Systems Only)	

Complete the following information for the certified components listed below which you installed. For beam 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 many of each you installed in this system.

g. <b>SELECTED COMPONENTS</b>				h. <b>OTHER CERTIFIED COMPONENTS</b> (Enter number of each installed in appropriate blocks.)		
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED		<input type="checkbox"/> X-RAY CONTROL	<input type="checkbox"/> CRADLE
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED		<input type="checkbox"/> HIGH VOLTAGE GENERATOR	<input type="checkbox"/> FILM CHANGER
TABLES	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED		<input type="checkbox"/> VERTICAL CASSETTE HOLDER	<input type="checkbox"/> IMAGE INTENSIFIER
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED		<input type="checkbox"/> TUBE HOUSING ASSEMBLY	<input type="checkbox"/> SPOT FILM DEVICE
CT GANTRY	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED		<input type="checkbox"/> DENTAL TUBE HEAD	<input type="checkbox"/> 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 manufacture(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, a copy of this form will be distributed to the state radiation health office and the facility of installation. A copy of this form will be maintained on file for five years from the date of installation.

a. PRINTED NAME	b. SIGNATURE	c. DATE
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### 6. COMMENTS