Distribution List:
Purchaser
Assembler
State Radiation Health Office

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: August 31, 2023
See Reverse for PRA statement

Assembler/Purchaser Control Number

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))*

- ☐ 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(s))*

- ☐ GENERAL PURPOSE RADIOGRAPHY
- ☐ GENERAL PURPOSE FLUOROSCOPY
- ☐ TOMOGRAPHY *(Other than CT)*
- ☐ ANGIOGRAPHY
- ☐ PODIATRY
- ☐ UROLOGY
- ☐ MAMMOGRAPHY
- ☐ CHEST
- ☐ CHIROPRACTIC
- ☐ CT HEADSCANNER
- ☐ CT WHOLE BODY SCANNER
- ☐ HEAD-NECK *(Medical)*
- ☐ DENTAL-INTRAORAL
- ☐ DENTAL-CEPHALOMETRIC
- ☐ DENTAL PANORAMIC
- ☐ RADIATION THERAPY SIMULATOR
- ☐ C-ARM FLUOROSCOPIC
- ☐ DIGITAL
- ☐ BONE MINERAL ANALYSIS
- ☐ DENTAL-CT
- ☐ OTHER *(Specify in comments)*

c. THE X-RAY SYSTEM IS *(Check one)*	d. THE MASTER CONTROL IS IN ROOM	e. DATE OF ASSEMBLY
☐ 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 CONTROL IS	b. CONTROL MANUFACTURER	d. CONTROL SERIAL NUMBER	e. DATE MANUFACTURED
☐ A NEW INSTALLATION ☐ EXISTING *(Certified)* ☐ EXISTING *(Non-certified)*	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. SELECTED COMPONENTS

	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED

h. OTHER CERTIFIED COMPONENTS
(Enter number of each installed in appropriate blocks.)

X-RAY CONTROL	CRADLE
HIGH VOLTAGE GENERATOR	FILM CHANGER
VERTICAL CASSETTE HOLDER	IMAGE INTENSIFIER
TUBE HOUSING ASSEMBLY	SPOT FILM DEVICE
DENTAL TUBE HEAD	FLUOROSCOPIC IMAGING ASSEMBLY
CEPHALOMETRIC DEVICE	IMAGE RECEPTOR
IMAGE RECEPTOR SUPPORT DEVICE	FLUOROSCOPIC AIR KERMA DISPLAY DEVICE
OTHER	

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 following completion of the assembly, a copy of this form will be submitted to the purchaser and, where applicable, to the State agency responsible for radiation protection.

a. PRINTED NAME	b. SIGNATURE

6. COMMENTS

Contact Information for State Radiation Health Offices is available on the website of the Conference of Radiation Control Program Directors (CRCPD), https://www.crcpd.org/mpage/Map
Form may be downloaded at: https://www.fda.gov/media/144454/download

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 18 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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