Form should NOT be submitted to FDA. See below for distribution list:

Distribution List:

State Radiation Health Office
Purchaser
Assembler

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: July 31, 2020
See Reverse for OMB 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(es))*

☐ GENERAL PURPOSE RADIOGRAPHY	☐ UROLOGY	☐ CT WHOLE BODY SCANNER	☐ RADIATION THERAPY SIMULATOR
☐ GENERAL PURPOSE FLUOROSCOPY	☐ MAMMOGRAPHY	☐ HEAD-NECK *(Medical)*	☐ C-ARM FLUOROSCOPIC
☐ TOMOGRAPHY *(Other than 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)*

- ☐ STATIONARY
- ☐ MOBILE

d. THE MASTER CONTROL IS IN ROOM

e. DATE OF ASSEMBLY

4. COMPONENT INFORMATION

a. THE MASTER CONTROL IS

- ☐ A NEW INSTALLATION
- ☐ EXISTING *(Certified)*
- ☐ 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. **SELECTED COMPONENTS**

	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
BEAM LIMITING DEVICE			
BEAM LIMITING DEVICE			
TABLES			
TABLES			
CT GANTRY			

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	☐ 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

6. COMMENTS