FOR FDA USE ONLY	DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service FOOD AND DRUG ADMINISTRATION **REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM**	Form Approved: OMB No. 0910-0025. Expiration Date: January 31, 2017 TEMPORARY Not an official copy and Not for submittal

1. EQUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED

2. ASSEMBLER INFORMATION

COMPANY INFORMATION

3. GENERAL INFORMATION

THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE

( ) 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

INTENDED USE(S)

[ ] General Purpose Radiology
[ ] General Purpose Fluoroscopy
[ ] Tomography *(other than CT)*
[ ] Angiography
[ ] Podiatry
[ ] Other
[ ] 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

THE X_RAY SYSTEM IS	THE MASTER CONTROL IS IN ROOM	DATE OF ASSEMBLY
( ) Stationary ( ) Mobile		

4. COMPONENT INFORMATION

THE MASTER CONTROL IS	CONTROL MANUFACTURER	CONTROL SERIAL NUMBER	DATE MANUFACTURED
( ) A New Installation ( ) Existing *(Certified)* ( ) Existing *(Non-certified)*			
	CONTROL MODEL NUMBER	**SYSTEM MODEL NAME** *(CT Systems Only)*	

	SELECTED COMPONENTS		
	MANUFACTURER	MODEL NUMBER	DATE MFR'ED
BEAM LIMITING DEVICE			
TABLES			
CT GANTRY			

OTHER CERTIFIED COMPONENTS *(Number of each installed)*

[ ] X-Ray Control
[ ] High Voltage Generator
[ ] Vertical Cassette Holder
[ ] Tube Housing Assembly
[ ] Dental Tube Head
[ ] Cephalometric Device
[ ] Image Receptor Support Device
[ ] Other
[ ] Cradle
[ ] Film Changer
[ ] Image Intensifier
[ ] Spot Film Device
[ ] Fluoroscopic Imaging Assembly
[ ] Image Receptor
[ ] Fluorocopic Air Kerma Display Device

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 manufacture(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 the 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.

PRINTED NAME	SIGNATURE	DATE

6. COMMENTS