

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 <div style="text-align:center; font-size: 1.2em; font-weight: bold;">TEMPORARY</div> Not an official copy and Not for submittal
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1. EQUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED
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2. ASSEMBLER INFORMATION

COMPANY INFORMATION

3. GENERAL INFORMATION

THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE	
<input type="checkbox"/> New Assembly-Fully Certified System <input type="checkbox"/> Reassembly-Fully Certified System	<input type="checkbox"/> Reassembly-Mixed System <i>(Both certified and non-certified components)</i> <input type="checkbox"/> Replacement Components in an Existing System <input type="checkbox"/> An Addition to an Existing System

INTENDED USE(S)			
<input type="checkbox"/> General Purpose Radiology <input type="checkbox"/> General Purpose Fluoroscopy <input type="checkbox"/> Tomography <i>(other than CT)</i> <input type="checkbox"/> Angiography <input type="checkbox"/> Podiatry <input type="checkbox"/> Other	<input type="checkbox"/> Urology <input type="checkbox"/> Mammography <input type="checkbox"/> Chest <input type="checkbox"/> Chiropractic <input type="checkbox"/> CT Headscanner	<input type="checkbox"/> CT Whole Body Scanner <input type="checkbox"/> Head-Neck <i>(medical)</i> <input type="checkbox"/> Dental-Intraoral <input type="checkbox"/> Dental-Cephalometric <input type="checkbox"/> Dental Panoramic	<input type="checkbox"/> Radiation Therapy Simulator <input type="checkbox"/> C-arm Fluoroscopic <input type="checkbox"/> Digital <input type="checkbox"/> Bone Mineral Analysis <input type="checkbox"/> Dental-CT

THE X-RAY SYSTEM IS <input type="checkbox"/> Stationary <input type="checkbox"/> Mobile	THE MASTER CONTROL IS IN ROOM	DATE OF ASSEMBLY
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4. COMPONENT INFORMATION

THE MASTER CONTROL IS <input type="checkbox"/> A New Installation <input type="checkbox"/> Existing <i>(Certified)</i> <input type="checkbox"/> Existing <i>(Non-certified)</i>	CONTROL MANUFACTURER	CONTROL SERIAL NUMBER	DATE MANUFACTURED
	CONTROL MODEL NUMBER	SYSTEM MODEL NAME <i>(CT Systems Only)</i>	

SELECTED COMPONENTS				OTHER CERTIFIED COMPONENTS <i>(Number of each installed)</i>	
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MFR'ED	<input type="checkbox"/> X-Ray Control <input type="checkbox"/> High Voltage Generator <input type="checkbox"/> Vertical Cassette Holder <input type="checkbox"/> Tube Housing Assembly	<input type="checkbox"/> Cradle <input type="checkbox"/> Film Changer <input type="checkbox"/> Image Intensifier <input type="checkbox"/> Spot Film Device
TABLES	MANUFACTURER	MODEL NUMBER	DATE MFR'ED	<input type="checkbox"/> Dental Tube Head <input type="checkbox"/> Cephalometric Device	<input type="checkbox"/> Fluoroscopic Imaging Assembly <input type="checkbox"/> Image Receptor
CT GANTRY	MANUFACTURER	MODEL NUMBER	DATE MFR'ED	<input type="checkbox"/> Image Receptor Support Device <input type="checkbox"/> Other	<input type="checkbox"/> Fluoroscopic 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
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6. COMMENTS

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