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: November 30, 2003 TEMPORARY

1. EQUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED

ABC Company
1111 First Street
Building 10
Rockville, 21704, US
Telephone:(111) 1111-1111

2. ASSEMBLER INFORMATION

COMPANY INFORMATION

DEF Company
2222 First Street
Building 20
Rockville, Province 9999999999, AR
Telephone:111 222 3333333333

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)

[X] General Purpose Radiology	[X] Urology	[X] CT Whole Body Scanner	[X] Radiation Therapy Simulator
[X] General Purpose Fluoroscopy	[X] Mammography	[X] Head-Neck *(medical)*	[X] C-arm Fluoroscopic
[X] Tomography *(other than CT)*	[X] Chest	[X] Dental-Intraoral	[X] Digital
[X] Angiography	[X] Chiropractic	[X] Dental-Cephalometric	[X] Bone Mineral Analysis
[X] Podiatry	[X] CT Headscanner	[X] Dental Panoramic	[X] Dental-CT

[X] Other: Other Intended use.

THE X_RAY SYSTEM IS	THE MASTER CONTROL IS IN ROOM	DATE OF ASSEMBLY
(•) Stationary ( ) Mobile	Room A	06/30/2008

4. COMPONENT INFORMATION

THE MASTER CONTROL IS

(•) A New Installation
( ) Existing *(Certified)*
( ) Existing *(Non-certified)*

CONTROL MANUFACTURER	CONTROL SERIAL NUMBER	DATE MANUFACTURED
CM	CSN	06/2007

CONTROL MODEL NUMBER	SYSTEM MODEL NAME *(CT Systems Only)*
CMN	CT SMN

SELECTED COMPONENTS

	MANUFACTURER	MODEL NUMBER	DATE MFR'ED
BEAM LIMITING DEVICE	MN B XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX	MDBXXXXXXXXXXXXXXXXXX XXX	06/2007
	MN	MD	
	MN	MD	
	MN	MD	
TABLES	MN T	MD T	06/2007
	MN	MD	
CT GANTRY	MN C	MD C	06/2007

OTHER CERTIFIED COMPONENTS *(Number of each installed)*

[1]	X-Ray Control	[6]	Cradle
[2]	High Voltage Generator	[7]	Film Changer
[3]	Vertical Cassette Holder	[8]	Image Intensifier
[4]	Tube Housing Assembly	[9]	Spot Film Device
[5]	Dental Tube Head	[10]	Fluoroscopic Imaging Assembly
[11]	Cephalometric Device	[12]	Image Receptor
[13]	Image Receptor Support Device	[14]	Fluorocopic Air Kerma Display Device

[15] Other: Other component

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
John Smith		06/30/2008

6. COMMENTS

Comments....
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