FOR FDA USE ONLY	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: December 31, 2008 See Reverse for OMB statement D 1254987

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 (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

- ☐ 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*

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	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
TABLES	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
CT GANTRY	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	☐ 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 manufacturer(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, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME | b. SIGNATURE | c. DATE

6. COMMENTS

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
Center for Devices and Radiological Health
1350 Piccard Drive (HFZ-240)
Rockville, MD 20850

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

FORM FDA 2579 (12/03)

GPO U.S. GOVERNMENT PRINTING OFFICE: 2005-316-669/10005

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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)*	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			
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
TABLES	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
CT GANTRY	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	☐ 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 manufacturer(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, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME	b. SIGNATURE	c. DATE

6. COMMENTS

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a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED

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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))*

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- ☐ 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))*

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☐ 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 (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

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- ☐ EXISTING *(Non-certified)*

b. CONTROL MANUFACTURER | d. CONTROL SERIAL NUMBER | e. DATE MANUFACTURED

c. CONTROL MODEL NUMBER | f. SYSTEM MODEL NAME *(CT Systems Only)*

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g. SELECTED COMPONENTS

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

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

☐ X-RAY CONTROL	☐ CRADLE
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2. ASSEMBLER INFORMATION

a. COMPANY NAME

b. STREET ADDRESS

c. CITY | d. STATE

e. ZIP CODE | f. TELEPHONE NUMBER ( )

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- ☐ MOBILE

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BEAM LIMITING DEVICE			
TABLES			
TABLES			
CT GANTRY			

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