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: August 31, 2023 See Reverse for PRA statement **D**

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(s))*

☐ GENERAL PURPOSE RADIOGRAPHY	☐ UROLOGY	☐ CT WHOLE BODY SCANNER	☐ RADIATION THERAPY SIMULATOR	☐ OTHER *(Specify in comments)*
☐ 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	☐ DENTAL-CT	

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

	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	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	FLUOROSCOPIC IMAGING ASSEMBLY
CEPHALOMETRIC DEVICE	IMAGE RECEPTOR
IMAGE RECEPTOR SUPPORT DEVICE	FLUOROSCOPIC AIR KERMA DISPLAY DEVICE
OTHER	

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, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME	b. SIGNATURE

6. COMMENTS

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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(s))*

☐ GENERAL PURPOSE RADIOGRAPHY	☐ UROLOGY	☐ CT WHOLE BODY SCANNER	☐ RADIATION THERAPY SIMULATOR	☐ OTHER *(Specify in comments)*
☐ 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	☐ DENTAL-CT	

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

	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	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	FLUOROSCOPIC IMAGING ASSEMBLY
CEPHALOMETRIC DEVICE	IMAGE RECEPTOR
IMAGE RECEPTOR SUPPORT DEVICE	FLUOROSCOPIC AIR KERMA DISPLAY DEVICE
OTHER	

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, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME	b. SIGNATURE

6. COMMENTS

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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 - 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(s))*

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☐ ANGIOGRAPHY	☐ CHIROPRACTIC	☐ DENTAL-CEPHALOMETRIC	☐ BONE MINERAL ANALYSIS	
☐ PODIATRY	☐ CT HEADSCANNER	☐ DENTAL PANORAMIC	☐ DENTAL-CT	

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)*

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b. INTENDED USE(S) *(Check appropriate box(es))*

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☐ STATIONARY ☐ MOBILE		(mm) (dd) (yyyy)

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	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED

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VERTICAL CASSETTE HOLDER	IMAGE INTENSIFIER
TUBE HOUSING ASSEMBLY	SPOT FILM DEVICE
DENTAL TUBE HEAD	FLUOROSCOPIC IMAGING ASSEMBLY
CEPHALOMETRIC DEVICE	IMAGE RECEPTOR
IMAGE RECEPTOR SUPPORT DEVICE	FLUOROSCOPIC AIR KERMA DISPLAY DEVICE
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