APPLICATION FOR OSHPD SPECIAL SEISMIC CERTIFICATION PREAPPROVAL (OSP)

OFFICE USE ONLY	
APPLICATION #:	OSP – 0357 – 10

OSHPD Special Seismic Certification Preapproval (OSP)

Type: ☒ New ☐ Renewal

Manufacturer Information

Manufacturer: Hitachi Medical Systems America

Manufacturer's Technical Representative: Aaron Pierce

Mailing Address: 1959 Summit Commerce Park, Twinsburg OH 44087

Telephone: (330) 425-1313 Email: PierceA@HitachiMed.com

Product Information

Product Name: Scenaria CT System

Product Type: Computed Tomograpghy (CT) Medical Diagnostic Imaging

Product Model Number: See Attachment 1, Table 1
(List all unique product identification numbers and/or part numbers)

General Description: Multiple component systems for the provision of Computed Tomography medical diagnostic imaging. Seismic Certification is limited to the systems and components identified in Attachment 1. *Seismic enhancement made to the test units and modifications required to address the anomalies observed during the tests shall be incorporated into the production units.*

Mounting Description: Floor (rigid base) mounted

Applicant Information

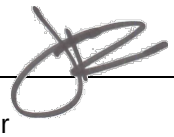
Applicant Company Name: **EASE Co.**

Contact Person: Jonathan Roberson, S.E.

Mailing Address: 5877 Pine Ave, Suite 210, Chino Hills, CA. 91709

Telephone: (909) 606-7622 Email: j.roberson@easeco.com

I hereby agree to reimburse the Office of Statewide Health Planning and Development review fees in accordance with the California Administrative Code, 2013.

Signature of Applicant:  Date: September 3, 2013

Title: Principal Engineer Company Name: EASE Co.

California Licensed Structural Engineer Responsible for the Engineering and Test Report(s)

Company Name: **EASE Co.**

Name: Jonathan Roberson, S.E. California License Number: S4197

Mailing Address: 5877 Pine Ave, Suite 210, Chino Hills, CA. 91709

Telephone: (909) 606-7622 Email: j.roberson@easeco.com

Supports and Attachments Preapproval

☐ Supports and attachments are preapproved under OPM- _____
(Separate application for OSHPD Preapproval of Manufacturer's Certification (OPM) of Supports and attachments is required)

☒ Supports and attachments are not preapproved

Certification Method

☐ Testing in accordance with: ☒ ICC-ES AC156

☐ Other (Please Specify): _____

Testing Laboratory

Company Name: Environmental Testing Laboratory, Inc.

Contact Name: Brady Richard

Mailing Address: 11034 Indian Trail, Dallas, TX 75229-3513

Telephone: (972) 247-9657 Email: brady@etldallas.com

Seismic Parameters

Design in accordance with ASCE 7-10 Chapter 13: ☒ Yes ☐ No

Design Basis of Equipment or Components (F_p/W_p) = See Attachment 1, Table 2

S_{DS} (Design spectral response acceleration at short period, g) = 1.25

a_p (In-structure equipment or component amplification factor) = See Attachment 1, Table 2

R_p (Equipment or component response modification factor) = See Attachment 1, Table 2

Ω_0 (System overstrength factor) = See Attachment 1, Table 2

I_p (Importance factor) = 1.5

z/h (Height factor ratio) = 1

Equipment or Component Natural Frequencies (Hz) = See Attachment 2

Overall dimensions and weight (or range thereof) = See Attachment 1, Table 1

Equipment or Components @ grade designed in accordance with ASCE 7-10 Chapter 15: ☐ Yes ☒ No

Design Basis of Equipment or Components (V/W) =

S_{DS} (Design spectral response acceleration at short period, g) =

S_{D1} (Design spectral response acceleration at 1 second period, g) =

R (Response modification coefficient) =

Ω_0 (System overstrength factor) =

C_d (Deflection amplification factor) =

I_p (Importance factor) = 1.5

Height to Center of Gravity above base =

Equipment or Component Natural Frequencies (Hz) =

Overall dimensions and weight (or range thereof) =

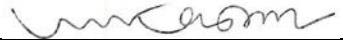
Tank(s) designed in accordance with ASME BPVC, 2010: ☐ Yes ☒ No

List of Attachments Supporting Special Seismic Certification

☒ Test Report(s) ☐ Drawings ☐ Calculations ☐ Manufacturer's Catalog

☒ Other(s) (Please Specify): Attachments 1 & 2

OSHPD Approval (For Office Use Only) – Approval Expires on December 31, 2019

Signature:  Date: 10/16/2013

Print Name: M. R. Karim Title: 10/16/2013

Special Seismic Certification Valid Up to : S_{DS} (g) = 1.25 z/h = 1.0

Condition of Approval (if applicable):

ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS

TABLE 1: SEISMIC CERTIFIED SYSTEMS & COMPONENTS

MANUFACTURER	**HITACHI MEDICAL CORPORATION**
SYSTEM	**SCENARIA 128-SLICE COMPUTED TOMOGRAPHY (CT) SYSTEM**

SYSTEM COMPONENT	PART NO.	DIMENSIONS (IN.) W	D	H	MAX WT (LB.)	MOUNT	BASIS[1]
CT Scanner Gantry	CT-WS-19	94	35	81	5170	FLOOR	UUT1
Patient Table [8]	CT-WT-19	25.5	110	19.5 to 42	1150 [3]	FLOOR	UUT2
Image Processing Unit	CT-IP-2	27	35	45	510	FLOOR	UUT3
AFC Industries Operators' Table	327590	48	30	29	122 [4]	FLOOR	UUT4
• Eizo Monitor	2490WUXI	22.5	8	18.25 to 21.5	23	CT-A CT [5] [6]	UUT4A
• Keyboard	KB229535	15.5	8.25	2.5	2.8	CT [5] [6]	UUT4B
• Microsoft Mouse	1043	---	---	---	---	CT [5] [6]	UUT4C
Operators' Console	CT-OC-19	8	25.5	17.5	45	FLOOR	UUT5

MOUNTING	FLOOR (Rigid Base): free-standing, base-mounted configuration with the component rigidly attached to a supporting structure and no lateral support above the base. CT (Countertop): refers to a condition where the unit sits atop but is not otherwise anchored to a counter, desk, or other piece of fixed furniture. CT-A (Countertop Anchored): refers to a condition where the unit is anchored to a counter, desk, or other piece of fixed furniture.
NOTES	1. Basis: UUT#: Indicates a test specimen matching these characteristics was tested as part of this evaluation. 2. All components are manufactured by Hitachi Medical Systems unless otherwise noted. 3. Weight for Scenaria Patient Table does not include 507 lb. patient load present during testing. 4. Weight includes the monitor, keyboard, and speaker present during testing. 5. Unanchored components may fall over during an actual earthquake and experience damage not observed during the limited testing conducted. It is strongly recommended that unanchored devices necessary for the operation of the system be secured to mitigate potential for damage and, as a condition of Seismic Qualification, a duplicate set of these devices shall be kept on hand at all times. 6. Data/power cords for unanchored devices shall be routed through cable management grommet in top of table/counter. 7. Test specimens included special features/enhancements not typically found in the standard production units. These modifications are necessary and essential conditions for Seismic Qualification. 8. Transverse motion of the Patient Table is excluded from Seismic Qualification. The test specimen was unable to demonstrate the full range of movement along the transverse axis of the patient table (+/- 70 mm from centerline) following completion of simulated seismic testing.

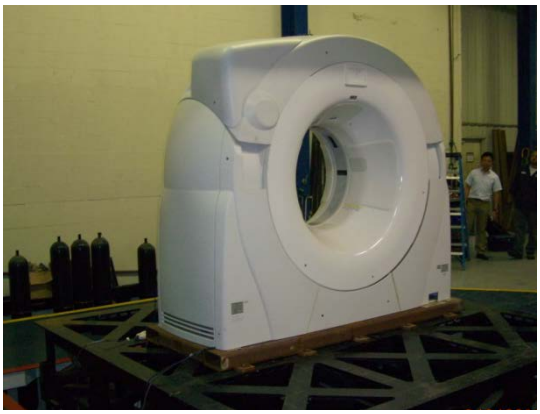
TABLE 2: ASCE 7-10 DESIGN BASIS FOR EQUIPMENT

COMPONENT	S_{DS}	z/h	F_P/ W_P	E_V	a_P	R_P	Ω_0
Gantry	1.25	1	1.50Wp	0.25Wp	1	1 ½	1 ½
Patient Table	1.25	1	1.50Wp	0.25Wp	1	1 ½	1 ½
Console/Computer/Image Processing Unit	1.25	1	0.90Wp	0.25Wp	2 ½	6	2 ½
Operators' table	1.25	1	0.90Wp	0.25Wp	1	2 ½	2 ½

ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT- 1 Scenaria CT Scanner Gantry Unit

MANUFACTURER:	Hitachi Medical Corporation
IDENTIFICATION:	Model No.: CT-WS-19
	Serial No.: KA11466101
DESCRIPTION:	System component of the Scenaria System
MOUNTING:	Rigid Base (Floor) Mounted using (4) – ½" Grade 8 bolts



PROPERTIES:

DIMENSIONS (in.)			Weight (lb.)	LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height		X-Axis	Y-Axis	Z-Axis
94	35	81	5170	5.0	8.5	18.6

SHAKE TABLE TEST PARAMETERS

CODE	TEST CRITERIA	S_{DS}	z/h	I_P	A_{FLX-H}	A_{RIG-H}	A_{FLX-V}	A_{RIG-V}
CBC 2013	ICC-ES AC156-12	1.25	1.0	1.5	2.00	1.50	0.84	0.34

Unit maintained structural integrity and functionality after the ICC-ES AC 156 test.

UUT-2 Patient Table

MANUFACTURER:	Hitachi Medical Corporation
IDENTIFICATION:	Model No.: CT-WT-19
	Serial No.: KA11469101
DESCRIPTION:	System component of the Scenaria System
MOUNTING:	Rigid Base (Floor) mounted using (5) – ½" dia Grade 5 bolts.

PROPERTIES:

DIMENSIONS (in.)			Weight (lb.)	LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height		X-Axis	Y-Axis	Z-Axis
25.5	110	19.5 min – 42 max	1150 + 507 patient load	1.2	>50	4.3

SHAKE TABLE TEST PARAMETERS

CODE	TEST CRITERIA	S_{DS}	z/h	I_P	A_{FLX-H}	A_{RIG-H}	A_{FLX-V}	A_{RIG-V}
CBC 2013	ICC-ES AC156-12	1.25	1.0	1.5	2.00	1.50	0.84	0.34

Unit maintained structural integrity and functionality after the ICC-ES AC 156 test except for a partial loss of motion along the transverse axis of the table. Test specimen demonstrated a +26mm/-45mm transverse movement from centerline following simulated seismic testing. Full range is transverse motion is reported as +70mm/-70mm.

UUT- 3 Image Processing Unit

MANUFACTURER:	Hitachi Medical Corporation
IDENTIFICATION:	Model No.: CT-IP-2
	Serial No.: KA102
DESCRIPTION:	System component of the Scenaria System
MOUNTING:	Rigid Base (Floor) Mounted using (4) – 3/8" dia Grade 8 bolts

PROPERTIES:

DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	X-Axis	Y-Axis	Z-Axis
27	35	45	510	14.6	12.9	13.9

SHAKE TABLE TEST PARAMETERS

CODE	TEST CRITERIA	S_{DS}	z/h	I_P	A_{FLX-H}	A_{RIG-H}	A_{FLX-V}	A_{RIG-V}
CBC 2013	ICC-ES AC156-12	1.25	1.0	1.5	2.00	1.50	0.84	0.34

Unit maintained structural integrity and functionality after the ICC-ES AC 156 test.

UUT-4 Operator table (including monitor, keyboard, mouse, and speaker)

MANUFACTURER:	Hitachi Medical Corporation			
IDENTIFICATION:	Device	Table	LCD Monitor	Keyboard
	Model No.	327590	2490WUXI	KB229535
DESCRIPTION:	AFC Industries, Inc Operators' Table with: • Eizo LCD Monitor anchored to table with Hitachi mounting brackets. • Hitachi keyboard & Microsoft mouse sitting atop table with cables routed through cable management grommet in table top.			
MOUNTING:	Operator's Table: Rigid Base (Floor) mounted using (4) – 3/8" diam. bolts to aluminum interface plate. Monitor: Countertop Anchored using (4) ¼" dia machine screws through top of table with washers and hex nuts below.			

PROPERTIES:

DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	X-Axis	Y-Axis	Z-Axis
48	30	29	122	16.5	12.3	22.5

SHAKE TABLE TEST PARAMETERS

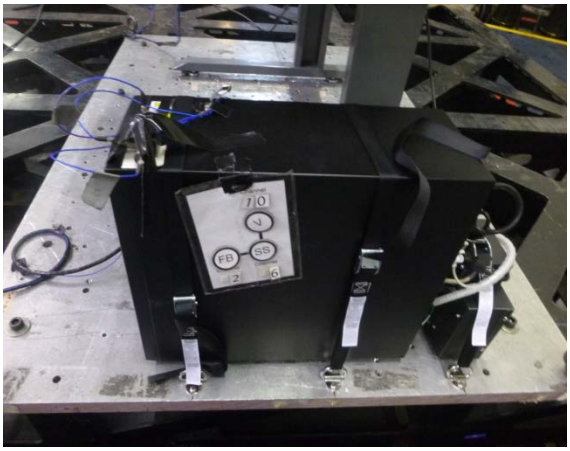
CODE	TEST CRITERIA	S_{DS}	z/h	I_P	A_{FLX-H}	A_{RIG-H}	A_{FLX-V}	A_{RIG-V}
CBC 2013	ICC-ES AC156-12	1.25	1.0	1.5	2.00	1.50	0.84	0.34

Unit maintained structural integrity and functionality after the ICC-ES AC 156 test.

ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT-5 Operator console

MANUFACTURER:	Hitachi Medical Corporation
IDENTIFICATION:	Model No.: CT-OC-19
DESCRIPTION:	System component of the Scenaria System
MOUNTING:	Rigid Base (Floor) mounted using • (3) – 1" Nylon Strap w/ metal cinch(220 lb working load) to • D-ring assembly w/ (2) – ¼" diam. machine screws per D-ring assembly (12 screws total)



PROPERTIES:

DIMENSIONS (in.)			Weight (lb.)	LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height		X-Axis	Y-Axis	Z-Axis
8	25.5	17.5	45	25.4	24.3	17.8

SHAKE TABLE TEST PARAMETERS

CODE	TEST CRITERIA	S_{DS}	z/h	I_P	A_{FLX-H}	A_{RIG-H}	A_{FLX-V}	A_{RIG-V}
CBC 2013	ICC-ES AC156-12	1.25	1.0	1.5	2.00	1.50	0.84	0.34

Unit maintained structural integrity and functionality after the ICC-ES AC 156 test.