

ROY COOPER • Governor MANDY COHEN, MD, MPH . Secretary MARK PAYNE • Director, Division of Health Service Regulation

July 25, 2019

Robert A. Leandro 301 Fayetteville Street, Suite 1400 Raleigh, NC 27602

No Review

Record #:

2959

Facility Name:

Haywood Regional Medical Center

FID #:

933234

Business Name:

DLP Haywood Regional Medical Center, LLC

Business #:

878

Project Description:

Acquire a CT scanner

County:

Haywood

Dear Mr. Leandro:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence and all additional information regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

You may need to contact the Agency's Radiation Protection and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne

Project Analyst

Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

cc:

Radiation Protection Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603 MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704 www.ncdhhs.gov/dhsr • TEL: 919-855-3873





Atlanta, GA Charleston, SC Charlotte, NC Columbia, SC Greenville, SC Raleigh, NC Spartanburg, SC

Robert A. Leandro
Partner
Telephone: 919.835.4636
Direct Fax: 919.834.4564

robbleandro@parkerpoe.com

July 19, 2019

VIA U.S. MAIL AND ELECTRONIC MAIL: Ena.lightbourne@dhhs.nc.gov

Ms. Ena Lightbourne Project Analyst Healthcare Planning and Certificate of Need Section North Carolina Department of Health and Human Services 2704 Mail Service Center Raleigh, North Carolina 27699-2704

RE: Additional Information Regarding Haywood Regional Medical Center Purchase of Used CT Scanner

Dear Ms. Lightbourne:

You have requested that Haywood provide additional information regarding the construction and installation costs associated with the purchase of the Used CT Scanner from GE. We can report that there were no costs associated with either construction or installation of this used unit.

Just as a brief reminder, in November of 2018, Haywood was approved to replace an existing CT Scanner at its hospital (Record No. 2785). At the time, Haywood traded in its existing CT Scanner and the trade-in value associated with its existing CT Scanner was credited toward the cost of the new CT Scanner. GE Healthcare took ownership of the existing CT Scanner. At the time GE took ownership of the used CT Scanner, both GE and Haywood took all regulatory steps to take the CT scanner off line and out of the active inventory of the hospital. See Attachment A. After some updates to the scanner, GE is now selling the used scanner back to Haywood for a total purchase price of 175,000.00. See Attachment B.

Based on this and our previously submitted information, please confirm that the Agency agrees that the above action does not require CON approval. I greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely,

That a. Labor

Robert A. Leandro

EXHIBIT A



DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOE

MANDY COHEN, MD, MPH SECRETARY

> MARK PAINE DIRECTOR

October 18, 2018

HAYWOOD REGIONAL MEDICAL CENTER MISTY LOVIN MANAGER OF IMAGING 262 LEROY GEORGE DR CLYDE NC 28721-7430

REF: ENCLOSED NOTIFICATION OF REGISTRATION NUMBER:

44-M000132

Your Hospital facility has 12 active tube(s) and a total of 12 x-ray tube(s) registered with this section.

Your Notification of Registration (NOR) has been issued and updated pursuant to the provisions of the 10A NCAC 15-North Carolina Regulations for Protection Against Radiation.

Change of Ownership or Relocation:

A new application must be completed when you relocate or change ownership of your practice and/or facility.

Updating your Notification of Registration:

When documenting changes and/or corrections draw a line through the old information and write in the new information;

When adding x-ray unit(s), fill in the blanks provided;

Identify the type of x-ray unit by checking the appropriate box or boxes.

As of January 1, 2009, all x-ray units that are designated as not in use on your registration will be billed in accordance to 10A NCAC 15.1105. The fees are based on the facility and the number of x-ray units that each facility possesses. If you dispose of or remove a not in use unit from your registration prior to July 1 you will not be billed for these machines. When disposing or removing the equipment, please utilize your NOR to notify our agency of the disposition of the x-ray units.

Please review and retain a copy of the NOR. Only submit the NOR if you have changes or updates to your registration. You must sign your NOR to authorize our agency to implement the requested updates and/or changes. Please email your NOR to XrayNORs@dhhs.nc.gov or contact the X-ray Registration Coordinator for assistance if you have questions regarding this matter.

Jenny Rollins, Manager Radiology Compliance Branch

my Kallina

RADIATION PROTECTION SECTION
WWW.NCRADIATION.NET

TEL 919-814-2250
LOCATION: 5505 CREEDMOOR RD • RALEIGH, NC 27612
MAILING ADDRESS: 1645 MAIL SERVICE CENTER • RALEIGH, NC 27699-1600
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

HAYWOOD REGIONAL MEDICAL CENTER

NORTH CAROLINA

NOTIFICATION OF REGISTRATION

Registration NO:

44 - M000132

(NOR) for X-ray Units

EFFECTIVE DATE: OCTOBER 18, 2018

SUPERSEDES THE PREVIOUS NOTIFICATION DATED: JUNE 04, 20:18

A signature is required to authorize our agency to update or amend a Notification of Registration. Please sign on the bottom of the page noted with changes to expedite the corrections. It is not necessary to sign every page. Unsigned forms will delay the registration process. Make changes and or corrections by drawing a line through the old information and write in the new information.

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		XrayNORs@dhhs.nc.gov	Registered Unit(s) For Changes email your signed NOR to XrayNORs@dhhs.nc.gov

	errited by Inspector.	or Official Use Only
Tage 1000	Date:	
RPS NOR Rev2/1	Accepted F	0

HAYWOOD REGIONAL MEDICAL CENTER

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For Official Use Only Verified by Inspector.

Date: Page 2 of 3

Accepted

RPS NOR Rev2/15 Rejected DATE:

SIGNATURE:

HAYWOOD REGIONAL MEDICAL CENTER

Accepted Rejected	Page 3 of 3	
	Date:	Verified by Inspector:
D AUTHORIZES CHANGES I CORRECTIONS: ON URY 10, 2018	Radiation Safety Officer (Required): Documentation of RSO's training and experience must be available for agency review. THE OWNER, RADIATION SAFETY OFFICER OR AUTHORIZED DESIGNEE SIGNS TO CERTIFY THIS INFORMATION IS ACCURATE AND AUTHORIZES CHANGES I CORRECTIONS: SIGNATURE: 10, 2018	Radiation Safety THE OWNER, RADIATION SAFETY OFFICER OR AU SIGNATURE:
35	ONLY submit the NOR if you have changes or updates! Please retain a copy for your records.	
Billing Address: HAYWOOD REGIONAL MEDICAL CENTER C/O LPNT ACCOUNTS PAYABLE PO BOX 282308 NASHVILLE TN 37228-8514 (877) 676-8861	Mailing Address: HAYWOOD REGIONAL MEDICAL CENTER ANN OTTUM IMAGING DIRECTOR 262 LEROY GEORGE DR CLYDE NC 28721-7430 (828) 452-8149 [8]	Physical Address: HAYWOOD REGIONAL MEDICAL CENTER MISTY LOVIN MANAGER OF IMAGING 262 LEROY GEORGE DR CLYDE NC 28721-7430 (828) 456-7311 Email: misty.lovin@haymed.org
State: Zipcode:	ray units: Individual/Business:City:Phone:	*List recipient of sold and/or donated x-ray units: Address:
Room # # of Tubes Date Installed Panoramic Cephalometric Bone Density Mammo Stereotatic Other:	Scopic CT Scanner C-Arm Intraoral Mammo Film Screen Mammo Digital	Add a Manufacturer Mode Mobile Digital Radiographic Fluore CR DR Mammo Tomosynthesis
CT 3018 11 28 2018 Room # # of Tubes Date Installed Panoramic © Cephalometric © Bone Density Mammo Stereotatic © Other:	1 (02(,-)4 S 3363 HMB I Number Control Serial Number Roscopic CT Scanner C-Arm Intraoral Mammo Film Screen Mammo Digital	Check all boxes that apply to the unit(s): Add a
Registration NO: 44 - M000132	CCENTER	HAT WOOD REGIONAL MEDICAL CENTER

FOR FDA USE ONLY

Digital Signature on File at FDA

1. EQUIPMENT LOCATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

2. ASSEMBLER INFORMATION

[0]

[1]

[0]

[0]

(0)

[0] Other

DATE MFR'ED

DATE MFR ED

Vertical Cassette

Dental Tube Head

Tube Housing

Cephalometric

Image Receptor

Support Device

Assembly

Device

Holder

[0] Image Intensifier

[0] Spot Film Device

Fluoroscopic Imaging Assembly

Image Receptor

Fluorocopic Air

Kerma Display Device

[0]

[0]

Form Approved: OMB No. 0910-0025. Expiration Date: May 31, 2010

H0135656

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED COMPANY INFORMATION Haywood Regional Hospital GE Healthcare 262 Leroy George Dr. 9900 Innovation Dr Mail Code 2176 Clyde, NC 28721, US Wauwatosa, WI 53226, US Telephone:(828) 456-7311 Telephone: (866) 736-3447 3. GENERAL INFORMATION THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE () Reassembly-Mixed System (Both certified and non-certified components) (a) New Assembly-Fully Certified System () Replacement Components in an Existing System () Reassembly-Fully Certified System () An Addition to an Existing System INTENDED USE(S) [] General Purpose Radiology [] Urology [X] CT Whole Body Scanner [] Radiation Therapy Simulator [] General Purpose Fluoroscopy [] Mammography Head-Neck (medical) C-arm Fluoroscopic [] [] Tomography (other than CT) Chest 1 1 1 Dental-Intraoral [X] Digital [] Angiography [] Bone Mineral Analysis [] Chiropractic [] Dental-Cephalometric [] Podlatry [] CT Headscanner [] Dental Panoramic [] Dental-CT [] Other THE X_RAY SYSTEM IS THE MASTER CONTROL IS IN ROOM DATE OF ASSEMBLY (*) Stationary () Mobile CT2018 11/28/2018 4. COMPONENT INFORMATION THE MASTER CONTROL IS CONTROL MANUFACTURER CONTROL SERIAL NUMBER DATE MANUFACTURED () A New Installation 513303HM8 10/2018 () Existing (Certified) CONTROL MODEL NUMBER SYSTEM MODEL NAME (CT Systems Only) () Existing (Non-certified) 5441626-14 828452CT1 SELECTED COMPONENTS OTHER CERTIFIED COMPONENTS (Number of each installed) MANUFACTURER MODEL NUMBER DATE MFR'ED [1] X-Ray Control [0] Cradle High Voltage [0] Film Changer BEAM LIMITING DEVICE Generator

5. ASSEMBLER CERTIFICATION

MANUFACTURER

MANUFACTURER

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	Chad Vande Hei	DATE
Shane Norman		Digitally Signed On: 05/05/2017, 10:22:12 AM	11/30/2018

6. COMMENTS

GANTRY

Comments:Performed new system install for Revolution Evo CT; GE Service Registration #:60-S000011; Max KVP:140; Max mA:600; System ld:828452CT1

MODEL NUMBER.

MODEL NUMBER



North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Richard O. Brajer Secretary

Mark Payne, Director Health Service Regulation

January 11, 2019

HAYWOOD REGIONAL MEDICAL CENTER

MISTY LOVIN MANAGER OF IMAGING
262 LEROY GEORGE DR

CLYDE NC 28721-7430

Registration Number: 044-M000132
Reference: Notice of Registration

The Radiology Compliance Branch received information regarding a installation and removal of X-ray equipment.

The North Carolina Regulations for Protection Against. Radiation 10A NCAC 15.0203 require an unregistered X-ray machine or facility to register such facility and each radiation machine within 30 days of initial operation of the facility and within 30 days of initial use of each X-ray unit. Specifically any information on X-ray equipment that has been added, replaced, removed or sold including to whom the equipment was transferred is required. In accordance with 10 A NCAC 15.0209 any registrant shall notify the agency in writing when any change will render the information contained in the application for registration or notice of registration no longer accurate.

Please verify accuracy of the following on this Notice of Registration. If you find a discrepancy, please identity that change on the NOR, you must sign and date for those corrections. Please send this information within 10 business days to the service e-mail account FDA2579@dhhs.nc.gov <mailto.FDA2579@dhhs.nc.gov>. Include in the email subject line: the facility name and your facility (NOR registration number.)

- * X-ray equipment Control Serial Number is used by RPS to identify equipment. The CSN is located on the on the control of each piece of X-ray equipment. The CSN should match the number recorded on Form FDA 2579 in field 4d, provided by the service provider for medical device installations. The CSN should be available in records of sale for non-medical devices.
- * The Install date of X-ray equipment is located on the install form and/or report of sale provided by your service provider. If a handheld unit was shipped, the date it was received at your facility is the install date.

Special Instructions:

Attached is a copy of the updated Notification of Registration (NOR) for X-ray Units for Haywood Regional Medical Center, registration number M000132, showing the updates made to the registration to remove the General Electric Lightspeed CT Scanner and add another General Electric CT Scanner.



Radiation Protection Section www.nedhhs.gov • www.neradiation.net
Tel 919-814-2250

Location: 5505 Creedmoor Road, Suite 100 • Raleigh, N.C. 27612
Mailing Address: 1645 Mail Service Center • Raleigh, N.C. 27699-1600
An Equal Opportunity / Affirmative Action Employer

3

We thank you for your cooperation in this matter.

Sincerely,

Diane Singleton

Diane Singleton X-Ray Registration Coordinator Division of Health Service Regulation Radiology Compliance Branch 1645 Mail Service Center Raleigh, NC 27966-1600 919-814-2250 Phone Reg #:

M000132

Status:

Reg-YES

0

Date Received:

Disclaimer:

RPS responses are based upon the information provided to RPS from the registrant or service provider. This response does not exclude compliance issues that may occur due to discovery during inspections that include observation of facility operations, staff interviews and document review.



Instructions for NOTIFICATION OF REGISTRATION (NOR) for X-ray Units

Instructions for Corrections to Notification of Registration

ALL forms submitted must be signed and dated, as unsigned forms will delay the registration process.

Contact Information Corrections

This includes changes to address (physical, mailing, billing) to include the address, point of contact, phone numbers, etc. This information can be found on the second page of the Notification of Registration.

Email the second page of this Notification of Registration with the changes to the contact information marked and signed by the indicated certifying official to: xrayNORS@dhhs.nc.gov

Add unit(s) not listed on Notification of Registration

This includes units that are installed and/or in use at your facility but are not listed on this Notification of Registration.

- Email an updated and signed unit addition form to: xrayNORS@dhhs.nc.gov
- Unit Addition forms are located on our website: www.ncradiation.net/Xray/applic.htm

Remove unit(s) listed on Notification of Registration

This includes units that have been sold, disposed of, or collected by service companies. These are units that are no longer on the premises of the registrant.

- Email an updated and signed unit removal form to: xravNORS@dhhs.nc.gov
- Unit removal forms are located on our website: www.ncradiation.net/Xray/applic.htm

Change of Ownership

The practice or facility is under new ownership.

- Email the completed and signed business application to: xrayNORS@dhhs.nc.gov
- Business applications are located on our website: www.ncradiation.net/Xray/applic.htm

EXHIBIT B



GE Precision Healthcare LLC FEIN: 83-0849145 9900 W Innovation Dr. Wauwatosa, WI 53226

SOLD TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL 262 LEROY GEORGE DR CLYDE NC 28721-7430

INVOICE 500742702

Invoice Amount \$140,000.00 Invoice Date: 16-Apr-2019 Due Date: 16-May-2019 Questions? Email: GEHCAR.Helpdesk@ge.com Phone: 1 (800) 581-5600

SHIP TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL CTR 262 LEROY GEORGE DR CLYDE NC 28721-7430

CUSTOMER ACCT#: 203185	CUSTOMER PO#: 203185
GEHC SALES REP OR FE: Charlotte Sales	CARRIER:
GEHC REFERENCE# (CONTRACT/SR/ORDER #): 4541185	WAYBILL:
BILLING TERMS: 80% on Delivery/ 20% on Acceptance or First Patient Use	PAYMENT TERMS: NET 30

Net Contract Price (w/o Tax) 678,698.53

Net Billed to Date (w/o Tax) 140,000.00

LINE#	ITEM#	DESCRIPTION		QTY	NET UNIT	PRICE	EXTENDED AMOUNT
		This is your 80% invoice					
1	TI-CT-TRADE-IN- NEW	TI_CT_TRADE_IN_NEW		1	140,	000.00	140,000.00
							*
		REMIT PAYMENT TO:	TOTAL				140,000.00
		: GE Precision Healthcare LLC : P.O. Box 96483	TAX				0.00
WIRE/E	FT INFORMATION	CHICAGO IL 60693 : ABA 04300096 ACCOUNT 1424892	SHIPPING	G/HAI	NDLING		0.00
EN	MAIL REMITTANCE	Remit.Healthcare@ge.com	TOTAL A	MOU	NT		140,000.00
MONTH	I, NOT TO EXCEED T	BJECT TO A SERVICE CHARGE OF 1.5% PER HE MAXIMUM RATE ALLOWED BY LAW. ALL HEALTHCARE TERMS AND CONDITIONS.	Please include	the Invo	oice / Credit N 5007427		umber for proper credit

Goods and services or reimbursements associated with the ordered products or services and provided under contract without separately identified charges constitute discounts or other reductions in price under applicable federal law. It is the customer's responsibility to disclose such discounts or other reductions in price in the manner required under state or federal program which provides reimbursement to the customer for or related to the products or services under the contract.



FEIN: 83-0849145 9900 W Innovation Dr. Wauwatosa, WI 53226

SOLD TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL 262 LEROY GEORGE DR CLYDE NC 28721-7430

INVOICE 500742847

	Inv	voice Amount
	\$3	5,000.00
Invoice	Date:	18-Apr-2019
Due Dat	e:	18-May-2019
		Questions?
Email:	GEHCA	AR.Helpdesk@ge.com
Phone:	1	(800) 581-5600

SHIP TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL CTR 262 LEROY GEORGE DR CLYDE NC 28721-7430

CUSTOMER ACCT#: 203185	CUSTOMER PO#: 203185	
GEHC SALES REP OR FE: Charlotte Sales	CARRIER:	
GEHC REFERENCE# (CONTRACT/SR/ORDER #): 4541185	WAYBILL:	Committee De Latin
BILLING TERMS: 80% on Delivery/ 20% on Acceptance or First Patient Use	PAYMENT TERMS: NET 30	

Net Contract Price (w/o Tax) 678,698.53

Net Billed to Date (w/o Tax) 35,000.00

LINE#	ITEM#	DESCRIPTION		QTY	NET UNIT P	RICE	EXTENDED AMOUNT
		This is your 20% invoice					
1	TI-CT-TRADE-IN- NEW	TI_CT_TRADE_IN_NEW		1	35,0	00.00	35,000.00
	PLEASE	REMIT PAYMENT TO:	TOTAL				35,000.00
	REMIT TO:	GE Precision Healthcare LLC P.O. Box 96483	TAX				0.00
WIRE/	EFT INFORMATION:	CHICAGO IL 60693 ABA 043000096 ACCOUNT 1424892	SHIPPING	G/HA	NDLING		0.00
		Remit.Healthcare@ge.com	TOTAL A	MOU	NT		35,000.00
MONT	H, NOT TO EXCEED TI	BJECT TO A SERVICE CHARGE OF 1.5% PER HE MAXIMUM RATE ALLOWED BY LAW. ALL HEALTHCARE TERMS AND CONDITIONS.	Please include	the inv	oice / Credit N 5007428		number for proper credit:

Goods and services or reimbursements associated with the ordered products or services and provided under contract without separately identified charges constitute discounts or other reductions in price under applicable fideral law. It is the customer's responsibility to discome such discounts or other reductions in price in the manner required under state or federal program which provides reimbursement to the customer for or related to the products or services under the contract.



GE Healthcare

9900 Innovation Drive Mail Code RP2176 Wauwatosa, WI 53226 USA



Haywood Regional Medical Center 262 Leroy George Dr Clyde, NC 28721

Dear Valued GE Customer:

Enclosed, please find a copy of FDA Form 2579 – Report of Assembly of a diagnostic x-ray system.

Why You Have Received a Copy of this Form:

The Food and Drug Administration (FDA) requires FDA Form 2579 be completed and filed with the Department of Health and Human Services (HHS) when a medical device that produces ionizing radiation:

- Is Installed
- Is Relocated
- Receives service that includes the replacement of a certified component, excluding the replacement of tubes (except in the States of Colorado and Minnesota)

Due to your recent installation, relocation, or service event, we have filed this form with HHS and are providing you with a copy as required by the regulation.

Please review the enclosed form for accuracy and report any problems to the GE contact listed below.

Please store this form so that you are able to produce it upon request during a state, federal, or other regulatory inspection of your facility.

Contact Information:

If you have additional questions regarding this form, please contact your GE Field Engineer or GE Quality Assurance at:

sendhhs@ge.com 866-736-3447





NOTIFICATION OF REGISTRATION (NOR) for X-ray Units

Facility Name:

HAYWOOD REGIONAL MEDICAL CENTER

Physical

MISTY LOVIN MANAGER OF IMAGING

Address:

262 LEROY GEORGE DR CLYDE, NC 28721-7430

(828) 456-7311

Email: misty.lovin@haymed.org

Registration #: 044-M000132

Effective Date: January 11, 2019

Superseded Date: October 18, 2018

Changes to facility name and physical address are to be made on the Business Application. http://ncradiation.net/xray/applic.htm

Most Responsible Person:

(physician, CEO, Financial Owner or Corporate Officer)

Please provide this information if blank. Contact name, mailing address.

Corporate name (if applicable)

led Harkeleroad, CEO 262 Le Ron George Dr.

RSO:

(radiation safety officer and address)

Please provide this information if blank.

Contact name, mailing address. Corporate name (if applicable)

(828) 452-8149

Name Print

(address that all correspondence will be mailed to) HAYWOOD REGIONAL MEDICAL CENTER ANN OTTUM IMAGING DIRECTOR 262 LEROY GEORGE DR CLYDE, NC 28721-7430

Business Manager:

(individual responsible for on-site general operations)

Please provide this information if blank.

Contact name, mailing address, Corporate name (if applicable)

Invoice Contact:

(annual invoice will be mailed to this person and address) HAYWOOD REGIONAL MEDICAL CENTER C/O LPNT **ACCOUNTS PAYABLE** PO BOX 282308 NASHVILLE, TN 37228-8514 (877) 676-8861

Retain this Document for Your Record

Upon initial receipt of your NOR; please review for accuracy. If you find typographical corrections, make those changes on this document.

Send email to XrayNORS@dhhs.nc.gov with your name, contact information and attach document.

If mailing document for typographical corrections after initial review; sign, date and mail to RPS.

THE OWNER OR AUTHORIZED DESIGNEE AUTHORIZES THESE CORRECTIONS

Preferred: X-Ray facility registrations and updates email to XrayNORS@dhhs.nc.gov Billing and Invoicing Questions email to RPSPayments@dhhs.nc.gov or leave voice message at 919-814-2274



NOTIFICATION OF REGISTRATION (NOR) for X-ray Units

EFFECTIVE DATE: January 11, 2019

SUPERSEDES THE PREVIOUS NOTIFICATION DATED: 10/18/2018

A signature is required to authorize our agency to update or amend a Notification of Registration . Unsigned forms will delay the registration process. Refer to the first page of this NOR for detailed instructions to amend your registration. Changes to contact information can be made on the second page of this NOR.

Units listed below are Registered

10 Units / Tubes 12

Unit#	Manufacturer	Model	S/N	Modality	Location
18276	OEC DIASONICS	9800	8S-0128	Bone Densitometry DEXA (dual energy x-ray absorptiometry)	MED DIAG - C-ARM # 1
	Tubes for this machine: 1	Active 1 Total		Installation Date: 03/06/2000	
20510	PHILIPS	9890 000 2403 98 960 1600 615	87303	Radiography Radiographic	MED DIAG - RM 4
	Tubes for this machine: 1	Active 1 Total	0.50	Installation Date: 05/17/2001	
33487	GE-OEC	9800	82-3655	Bone Densitometry DEXA (dual energy x-ray absorptiometry)	MED DIAG - RM C-ARM # 3
	Tubes for this machine: 1	Active 1 Total		Installation Date: 10/14/2005	
38788	GENERAL ELECTRIC	AMX-4 PLUS 2275938-7	1012980WK7	Radiography – Radiographic	MED DIAG - MOBILE
	Tubes for this machine: 1	Active 1 Total		Installation Date: 09/10/2007	
47788	PHILIPS	9896-002-00541	1653	Fluoroscopy C-Arm	MED DIAG - CATH LAB 1
	Tubes for this machine: 1	Active 1 Total		Installation Date: 06/10/2011	
55110	GE-OEC	888169-01	ES-3241	Bone Densitometry DEXA (dual energy x-ray absorptiometry)	MED DIAG - RM C-ARM # 4 -
	Tubes for this machine: 1	Active 1 Total		Installation Date: 08/11/2014	MOBILE
63541	GENERAL ELECTRIC	5277061	HL02YS8T /	Radiography Radio/ Fluoro	MED DIAG - RM
	Tubes for this machine: 2	Active 2 Total		Installation Date: 02/15/2018	
53976	GENERAL ELECTRIC	5270661	AJFOEE	Radiography – Radio/ Fluoro	MED DIAG - RM
	Tubes for this machine: 2	Active 2 Total		Installation Date: 02/15/2018	
54833	GE-OEC	00-881190-07	E2XXXX06622	Fluoroscopy C-Arm	MED DIAG - C-ARM # 5
	Tubes for this machine: 1	Active 1 Total		Installation Date: 10/17/2018	071111111111
65345	GENERAL ELECTRIC Tubes for this machine: 1	5441626-14 Active 1 Total	513303HM8	CT Scanner – CT	CT 2018
Units list	ed below are Removed-	Disposed	1 Units / T	ubes 0	
Unit#	Manufacturer	Model	S/N	Modality	Location
37347	GENERAL ELECTRIC	LIGHTSPEED VCT 5115335	449743CN4	CT Scanner – CT	MED DIAG - RM CT2

HAYWOOD REGIONAL MEDICAL

Registration #: 044-M000132

Tubes for this machine: 0 Active | 0 Total

Installation Date: 03/02/2007

			and the second s	
For Official Use Only				
Verified by Inspector:)ate:	Ш	Accepted	Rejected

FOR FDA USE ONLY

Digital Signature on File at FDA

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: May 31, 2010

H0144540

1. EQUIPMENT LOCATION 2. ASSEMBLER INFORMATION HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED COMPANY INFORMATION Haywood Regional Medical Center GE Healthcare 262 Leroy George Dr 9900 Innovation Dr Mail Code 2176 Clyde, NC 28721, US Wauwatosa, WI 53226, US Telephone: (828) 456-7311 Telephone:(866) 736-3447 3. GENERAL INFORMATION THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE () Reassembly-Mixed System (Both certified and non-certified components) () New Assembly-Fully Certified System (*) Replacement Components in an Existing System () Reassembly-Fully Certified System () An Addition to an Existing System INTENDED USE(S) [X] General Purpose Radiology [] Radiation Therapy Simulator [] Urology [] CT Whole Body Scanner [] 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 [] Dental Panoramic [] CT Headscanner [] Dental-CT [] Other THE X_RAY SYSTEM IS THE MASTER CONTROL IS IN ROOM DATE OF ASSEMBLY (*) Stationary () Mobile X-ray 04/09/2019 4. COMPONENT INFORMATION THE MASTER CONTROL IS CONTROL MANUFACTURER CONTROL SERIAL NUMBER DATE MANUFACTURED () A New Installation 87303 04/2001 () Existing (Certified) CONTROL MODEL NUMBER SYSTEM MODEL NAME (CT Systems Only) () Existing (Non-certified) **Bucky Diagnost** SELECTED COMPONENTS OTHER CERTIFIED COMPONENTS (Number of each installed) MANUFACTURER MODEL NUMBER DATE MFR'ED [0] X-Ray Control [01 Cradle **Philips** 989601000615 06/2000 [0] High Voltage [0] Film Changer BEAM LIMITING DEVICE Generator Vertical Cassette [0] [0] Image Intensifier Holder **Tube Housing** [0] [0] Spot Film Device Assembly MANUFACTURER MODEL NUMBER DATE MFR'ED [0] Dental Tube Head [0] Fluoroscopic Imaging Assembly Cephalometric Device [0] [0] Image Receptor MANUFACTURER MODEL NUMBER DATE MFR'ED [01 Image Receptor [0] Fluorocopic Air GANTRY Support Device Kerma Display Device [0] 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 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 Chad Vande Hei Bradley Catherman 04/16/2019 Digitally Signed On: 05/05/2017, 10:22:12 AM

6. COMMENTS

GE Service Registration #:60-S000011; Max KVP:150; Max mA:1000; System Id:828452MVBUCKY

SCHEDULE 1

Items to be removed from Quotation # PR13-C18656 & Purchase Order # 203185

Part # Description Qty (#)

TI-CT-TRADE-IN-NEW RENOVATE PROMO Trade In of LightSpeed VCT -1

Net change in order value: \$\$175,000.00

GE Reference: CO-29152

Lightbourne, Ena

From:

Lightbourne, Ena

Sent:

Monday, June 03, 2019 9:08 AM

To:

Leandro, Robert A.

Subject:

Request for a No Review for Haywood Regional _ request for information

Good Morning Mr. Leandro,

Request for Additional Information

Facility:

Haywood Regional Medical Center Description: Acquire a CT scanner

Project County:

Haywood

FID:

933234

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter dated May 22, 2019, regarding development of the above referenced project. In order for the Agency to make a determination regarding your request, please submit the following additional information.

• The cost for construction or renovation of space, installations, etc., associated with this project.

Upon receipt of the above information, the Agency will provide a response to your request. If you have any questions regarding this matter, please do not hesitate to call me at 919-855-4610.

Thank you,

Ena,

Ena Lightbourne

Certificate of Need, Project Analyst

<u>Division of Health Service Regulation</u>, Healthcare Planning and Certificate of Need Section

<u>NC Department of Health and Human Services</u>

Office: 919-855-4610

Ena.lightbourne@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, North Carolina 27699-2704

Twitter | Facebook | YouTube | LinkedIn

Parker Poe

Atlanta, GA
Charleston, SC
Charlotte, NC
Columbia, SC
Greenville, SC
Raleigh, NC
Spartanburg, SC

Robert A. Leandro
Partner
Telephone: 919.835.4636
Direct Fax: 919.834.4564
robbleandro@parkerpoe.com

May 22, 2019

VIA U.S. MAIL AND ELECTRONIC MAIL: martha.frisone@dhhs.nc.gov

Martha Frisone Chief Healthcare Planning and Certificate of Need Section North Carolina Department of Health and Human Services 2704 Mail Service Center Raleigh, North Carolina 27699-2704

RE: Request for No Review Determination Regarding Haywood Regional Medical Center Purchase of Used CT Scanner

Dear Ms. Frisone:

Our law firm represents Haywood Regional Medical Center ("Haywood"). I am writing to provide notice to the Healthcare Planning and Certificate of Need Section that Haywood is planning to purchase a used CT Scanner at fair market value, which does not exceed the threshold dollar amount for major medical equipment under N.C. Gen. Stat. § 131E-176(14o). We are requesting that the CON Section confirm that the purchase of the used CT Scanner does not meet the definition of major medical equipment under N.C. Gen. Stat. § 131E-176(14o) and as such, does not require CON review.

RELEVANT FACTS

In November of 2018, Haywood was approved to replace an existing CT Scanner at its hospital (Record No. 2785). At the time, Haywood traded in its existing CT Scanner and the trade-in value associated with its existing CT Scanner was credited toward the cost of the new CT Scanner. GE Healthcare took ownership of the existing CT. As noted in Haywood's request, Haywood indicated that it was possible that it may seek to re-acquire the CT Scanner that it traded in from the vendor at some later date. Haywood would now like to re-purchase this CT Scanner from its GE Healthcare.

The total capital cost of repurchasing this used CT Scanner will be \$175,000.00. See Exhibit A, which includes copies of two invoices from the vendor, GE Healthcare, reflecting that 80% of the total purchase price is due upon delivery and the remaining 20% is due upon acceptance or first patient use. The total capital cost of the used CT Scanner will be \$175,000.00. *Id*.

ANALYSIS

Based on the above facts, we believe that the acquisition of a used CT Scanner at fair market value (\$175,000.00) does not require CON review. Namely, the proposed acquisition does not meet the definition of major medical equipment under N.C. Gen. Stat. § 131E-176(14o).

The applicable statute defines "major medical equipment" as follows:

"Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred and fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred and fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.

Based upon the above facts, the CT Scanner does not meet the definition of major medical equipment because the total capital cost is less than \$750,000.

Please confirm that the Agency agrees with our assessment and that the above action does not require CON approval. I greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely,

Robert A. Leandro

Rober a. 20

EXHIBIT A Invoices

ATTACHED



GE Precision Healthcare LLC FEIN: 83-0849145 9900 W Innovation Dr. Wauwatosa, WI 53226

SOLD TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL 262 LEROY GEORGE DR CLYDE NC 28721-7430

INVOICE 500742847

Invoice Amount

\$35,000.00

Invoice Date:

18-Apr-2019

Due Date:

18-May-2019

Questions?

Email: Phone: GEHCAR.Helpdesk@ge.com

1 (800) 581-5600

SHIP TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL CTR 262 LEROY GEORGE DR CLYDE NC 28721-7430

CUSTOMER ACCT#: 203185	CUSTOMER PO#: 203185			
GEHC SALES REP OR FE: Charlotte Sales	CARRIER:			
GEHC REFERENCE# (CONTRACT/SR/ORDER #): 4541185	WAYBILL:			
BILLING TERMS: 80% on Delivery/ 20% on Acceptance or First Patient Use	PAYMENT TERMS: NET 30			

Net Contract Price (w/o Tax) 678,698.53

Net Billed to Date (w/o Tax) 35,000.00

LINE #	ITEM#	DESCRIPTION	QTY	NET UNIT I	PRICE	EXTENDED AMOUNT
		This is your 20% invoice				
1	TI-CT-TRADE-IN- NEW	TI_CT_TRADE_IN_NEW	1	35,	00.00	35,000.00
		*		39		
		3	*			
	e:					
Marin Ski	PLEASE	REMIT PAYMENT TO:				25 000 00

PLEASE REMIT PAYMENT TO: REMIT TO: GE Precision Healthcare LLC US MAIL: P.O. Box 96483 CHICAGO IL 60693 WIRE/EFT INFORMATION: ABA 043000096 ACCOUNT 1424892

EMAIL REMITTANCE: Remit.Healthcare@ge.com

TOTAL 35,000.00 TAX 0.00 SHIPPING/HANDLING 0.00 TOTAL AMOUNT 35,000.00

MONTH, NOT TO EXCEED THE MAXIMUM RATE ALLOWED BY LAW, ALL ORDERS SUBJECT TO GE HEALTHCARE TERMS AND CONDITIONS.

PAST DUE INVOICES ARE SUBJECT TO A SERVICE CHARGE OF 1.5% PER | Please include the Invoice / Credit Memo number for proper credit: 500742847

Goods and services or reimbursements associated with the ordered products or services and provided under contract without separately identified charges constitute discounts or other reductions in price under applicable federal law. It is the customer's responsibility to disclose such discounts or other reductions in price in the manner required under state or federal program which provides reimbursement to the customer for or related to the products or services under the contract.



GE Precision Healthcare LLC FEIN: 83-0849145 9900 W Innovation Dr. Wauwatosa, WI 53226

SOLD TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL 262 LEROY GEORGE DR CLYDE NC 28721-7430

INVOICE 500742702

Invoice Amount

\$140,000.00

Invoice Date:

16-Apr-2019

Due Date:

16-May-2019

Questions?

Email:

GEHCAR.Helpdesk@ge.com

Phone:

1 (800) 581-5600

SHIP TO:

HAYWOOD REGIONAL MEDICAL CENTER HAYWOOD REGIONAL MEDICAL CTR 262 LEROY GEORGE DR CLYDE NC 28721-7430

CUSTOMER ACCT#: 203185	CUSTOMER PO#: 203185			
GEHC SALES REP OR FE: Charlotte Sales	CARRIER:			
GEHC REFERENCE# (CONTRACT/SR/ORDER #): 4541185	WAYBILL:			
BILLING TERMS: 80% on Delivery/ 20% on Acceptance or First Patient Use	PAYMENT TERMS: NET 30			

Net Contract Price (w/o Tax) 678,698.53

Net Billed to Date (w/o Tax) 140,000.00

LINE #	ITEM#	DESCRIPTION	QTY	NET UNIT PRICE	EXTENDED AMOUNT
		This is your 80% invoice			
1	TI-CT-TRADE-IN- NEW	TI_CT_TRADE_IN_NEW	1	140,000.00	140,000.00
	PLEASE	REMIT PAYMENT TO:			140 000 00

REMIT TO: GE Precision Healthcare LLC US MAIL: P.O. Box 96483

CHICAGO IL 60693

WIRE/EFT INFORMATION: ABA 043000096 ACCOUNT 1424892

EMAIL REMITTANCE: Remit.Healthcare@ge.com

140,000.00 TOTAL TAX 0.00 SHIPPING/HANDLING 0.00 **TOTAL AMOUNT** 140,000.00

PAST DUE INVOICES ARE SUBJECT TO A SERVICE CHARGE OF 1.5% PER Please include the Invoice / Credit Memo number for proper credit: MONTH, NOT TO EXCEED THE MAXIMUM RATE ALLOWED BY LAW. ALL ORDERS SUBJECT TO GE HEALTHCARE TERMS AND CONDITIONS.

500742702

Goods and services or reimbursements associated with the ordered products or services and provided under contract without separately identified charges constitute discounts or other reductions in price under applicable federal law. It is the customer's responsibility to disclose such discounts or other reductions in price in the manner required under state or federal program which provides reimbursement to the customer for or related to the products or services under the contract.