

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

-CORRECTION-

April 7, 2021

Dorsey Tobias

Dorsey.tobias@unchealth.unc.edu

Exempt from Review - Replacement Equipment

Record #: 3262

Date of Request: April 14, 2020

Facility Name: Nash General Hospital

FID #: 933368

Business Name: Nash Hospitals, Inc.

Business #: 1289

Project Description: Replace CT scanner

County: Nash

Dear Ms. Tobias:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the GE Healthcare Rev HDe6 ES CT scanner to replace the existing GE Healthcare Lightspeed Pro 32 VCT Control CT scanner model 5115335-12, Serial # 1637YC8. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Gregory F. Yakaboski

Gloria G. Hale

Project Analyst

Gloria C. Hale

Team Leader, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR

Radiation Protection Section, DHSR

Construction 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

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873



2460 Curtis Ellis Drive, Rocky Mount, NC 27804 252 962-8000 / www.nashu3nchealthcare.org

March 17, 2021

Via E-MAIL

Greg Yakaboski, Project Analyst, Certificate of Need N.C. Department of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603

RE: Nash UNC Health Care

Replacement of Existing CT Scanner

Seeking CON Exemption NCGS 131E-184(a)(7) Rocky Mount, NC (FID 933368; Nash County)

Dear Mr. Yakaboski,

On April 14, 2020, I wrote the attached letter seeking a determination of exemption from Certificate of Need review for the replacement of a CT scanner at Nash Health Care Systems (d.b.a. "Nash UNC Health Care", "Nash UNC"). On April 20, 2020, I received the attached letter confirming exemption in accordance with N.C. Gen. Stat. §131E-184(a)(7), based on the fact that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

As we have completed a Master Facilities Plan and neared implementation of the CT replacement, we have determined a need to change course with which CT scanner we will replace, based on patient flow patterns. In our prior letter and supporting documents, the existing CT scanner referenced was the GE Healthcare Lightspeed Pro 32 VCT Control model 5115335-12, Serial #: 1660YCO. We are now hoping to maintain that CT scanner, and instead replace the existing GE Healthcare Lightspeed Pro 32 VCT Control model 5115335-12, Serial #: 1637YC8. The purchased (new) CT scanner remains the same. The existing unit that we are replacing will be sold or disposed of when the new scanner is operational, and will not be used again in the State without first obtaining a certificate of need if one is required.

I have attached the supporting documents which now include the updated information for the CT scanner we are planning to replace.

Nash UNC hereby requests that the Agency provide a written response confirming that the change in which CT scanner we are replacing, as documented in the attached materials, does not require additional review. If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this request.

Sincerely,

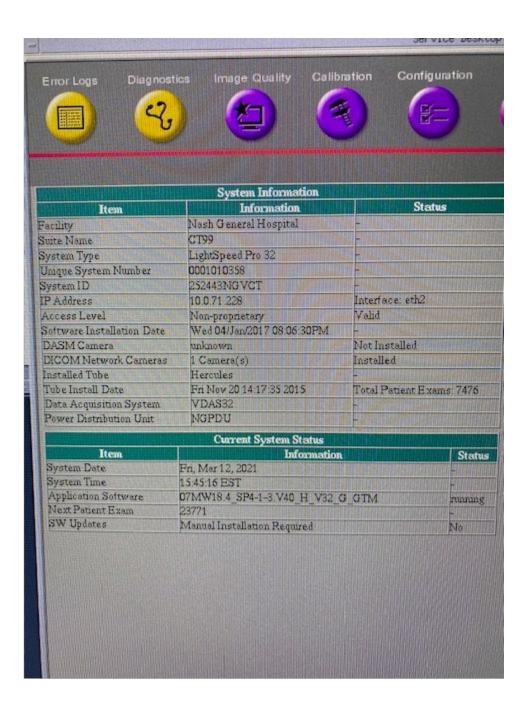
Dorsey Tobias Executive Director, Marketing, Communications & Strategy Nash UNC Health Care

Enclosures

Model and Serial Number identifier on the back of the Lightspeed Pro 32 Control Monitor at NGH and will match State's ROA:



Console Picture on NGH Lightspeed Pro 32 verifying System ID that correlates with GE iCenter reports (system date and time shows system is operational)



Gantry Labels



EQUIPMENT COMPARISON

EQUIFINIENT CONTANISON	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	GE Healthcare	GE Healthcare
Model number	Lightspeed Pro 32 VCT	Rev HDe6 ES
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Control Model #: 5115335-12 Serial #: 1637YC8	Pending Receipt of Report of Assembly
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2006	2020
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	Unavailable	\$23,493
Total cost of the equipment	Unavailable	\$736,670.98
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	Nash UNC Hospital	Nash UNC Hospital
Document that the existing equipment is currently in use	Attached	NA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	 Head, neck, chest, abd and pelvis CT imaging Lung Cancer screening CTA head, neck, chest, abd, pelvis and ileofemoral run offs CT upper and lower extremities CT Fluoro 	NA
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	NA	All exams except CT fluoro

Date of last revision: 5/17/19

FOR FDA USE ONLY	DEPA	H HOSPITALS,	INC.	252 443 8880 P. Ø4 Form Approved: OMB No. 0910-0213					
PORT DA USE ORET	Public Health Service			Expiration Date: Decer See Reverse for OMB	lecember 31, 2001 DMB statement				
		REPORT OF	MINISTRATION ASSEMBLY	G155552	+11				
EQUIPMENT LOCATIO	N N	OF A DIAGNOSTIC							
NAME OF HOSPITAL DOCTOR OR OFFICE	WHERE INSTALLED		2. ASSEMBLER I	NFORMATION	7				
STREET ADDRESS			GE Med Systems						
2460 Curtis Ellis Dr			N25 W23255 Pau	I Rd FSCT W598					
Rocky Mount		d. STATE NC	c. aty	c. CITY C. STATE WI					
27804	252-443-8992	1.10	Pewaukee . zip cooe 53072	1. TELEPHONE MUN 866.736.34	0ER 147				
3. GENERAL INFORMA			33072						
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PODIATRY		CT HEADSCANNER	DENTAL PANARAN		THER (Specify in comments)				
c. THE X-RAY SYSTEM IS (Check or X STATIONARY MOBILE	ne)	d. THE MASTER CO	NTROLIS IN ROOM	e. DATE OF ASSEMBL 1/5/2006 (mm) (dd)					
4. COMPONENT INFO	RMATION (If addition	nal space is need	ed for this section use anothe	er form, replacing the	preprinted -				
number with this Form	Number, and comp	lete Items 1, 4, an	d 5 only) c. CONTROL SERIAL NUMBER	l e.Di	TE MANUFACTURED				
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			11						
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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

H0160126

JUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED Nash General Hospitt 2460 CURTIS ELLIS DR Rocky Mount, NC 27804, US Telephone:(252) 962-8991

2. ASSEMBLER INFORMATION

COMPANY INFORMATION

GE Healthcare

9900 Innovation Dr Mail Code 2176

Wauwatosa, WI 53226, US

DATE MFR'ED

DATE MFR'ED

[0]

[0]

[0] Other

3. GEN	NERAL INFORMATION	ON				16	epnone:(8	66) 736-34	147					
	PORT IS FOR ASSEMBLY OF		MPONEN	TS 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											
	Tender T		Mammography Chest Chiropractic	[X] CT Wh [] Head-? [] Dental		Head-Neck Dental-Intra Dental-Cep	/hole Body Scanner -Neck (medical)		[] Radii [] C-arr [X] Digit		Mineral Analysis			
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	CONTROL MODEL NUMBER			SYSTEM MODEL NAME CT Lightspeed VCT						(CT Systems Only)				
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<u> </u>									10		be Housing sembly		0]	Spot Film Device

5. ASSEMBLER CERTIFICATION

MANUFACTURER

MANUFACTURER

TABLES

GANTRY

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.

MODEL NUMBER

MODEL NUMBER

PRINTED NAME	SIGNATURE	Chad Vande Hei	DATE
Jeffrey Jackson		Digitally Signed On: 05/05/2017, 10:22:12 AM	01/07/2020

6. COMMENTS

GE Service Registration #:60-S000011; Max KVP:140; Max mA:800; System Id:252443NGVCT

Fluoroscopic Imaging Assembly

[0] Image Receptor

[0] Fluorocopic Air Kerma Display

Device

[0] Dental Tube Head [0]

Cephalometric

Image Receptor Support Device

Device

From: Yakaboski, Greg
To: Waller, Martha K

Subject: FW: [External] RE: 3262 Nash Nash General Hospital 933368 Exemption

Date: Monday, March 22, 2021 4:13:39 PM

Attachments: <u>image001.png</u>

3262 Nash Nash General Hospital 933368 Exemption Request.pdf

CT Replacement (2) - Replacement Equipment Comparison Form2021.docx

CT replacement (2) - Model SN System ID.docx CT replacement (2) - Report of Assembly .pdf

Nash UNC - Replacement CT Letter - change of CT being replaced.docx

Nash UNC - Replacement CT Letter.docx

Martha.... This is an exemption request that I received on Wednesday.

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski

Project Analyst

Division of Health Service Regulation, Certificate of Need

NC Department of Health and Human Services

Help protect your family and neighbors from COVID-19.

Know the 3 Ws. Wear. Wait. Wash.

#StayStrongNC and get the latest at nc.gov/covid19

Office: 919-855-3873

Greg.Yakaboski@dhhs.nc.gov

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

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From: Tobias, Dorsey < Dorsey. Tobias@unchealth.unc.edu>

Sent: Wednesday, March 17, 2021 2:35 PM

To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Subject: [External] RE: 3262 Nash Nash General Hospital 933368 Exemption

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

Greg – Per our discussion earlier this week, below is the letter outlining our request. All supporting materials are attached. I sent you the RoboKiller app on Monday – did you receive that? Hope it works out for you!

Thank you for your help. Dorsey

Dear Mr. Yakaboski,

On April 14, 2020, I wrote the attached letter seeking a determination of exemption from Certificate of Need review for the replacement of a CT scanner at Nash Health Care Systems (d.b.a. "Nash UNC Health Care", "Nash UNC"). On April 20, 2020, I received the attached letter confirming exemption in accordance with N.C. Gen. Stat. §131E-184(a)(7), based on the fact that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

As we have completed a Master Facilities Plan and neared implementation of the CT replacement, we have determined a need to change course with which CT scanner we will replace, based on patient flow patterns. In our prior letter and supporting documents, the existing CT scanner referenced was the GE Healthcare Lightspeed Pro 32 VCT Control model 5115335-12, Serial #: 1660YCO. We are now hoping to maintain that CT scanner, and instead replace the existing GE Healthcare Lightspeed Pro 32 VCT Control model 5115335-12, Serial #: 1637YC8. The purchased (new) CT scanner remains the same. The existing unit that we are replacing will be sold or disposed of when the new scanner is operational, and will not be used again in the State without first obtaining a certificate of need if one is required.

I have attached the supporting documents which now include the updated information for the CT scanner we are planning to replace.

Nash UNC hereby requests that the Agency provide a written response confirming that the change in which CT scanner we are replacing, as documented in the attached materials, does not require additional review. If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this request.

Sincerely,

Dorsey Tobias Executive Director, Marketing, Communications & Strategy Nash UNC Health Care **Dorsey Tobias** | Executive Director

Marketing, Communications & Strategy

Nash UNC Health Care

2460 Curtis Ellis Drive, Rocky Mount, NC 27804

O: 252.962.8900 | M: 252.904.2524 dorsev.tobias@unchealth.unc.edu



From: Waller, Martha K < martha.waller@dhhs.nc.gov >

Sent: Monday, April 20, 2020 2:20 PM

To: Tobias, Dorsey < <u>Dorsey.Tobias@unchealth.unc.edu</u>>

Subject: FW: 3262 Nash Nash General Hospital 933368 Exemption

Ext Mail: open links/attachments w/caution

Martha Waller

Administrative Specialist 1

Division of Health Service Regulation, Certificate of Need Section North Carolina Department of Health and Human Services

Main: 919-855-3873 Office: 919-855-3885

martha.waller@dhhs.nc.gov

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

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From: Waller, Martha K

Sent: Monday, April 20, 2020 2:18 PM

To: 'dorsey.tobias@unchelath.unc.edu' <dorsey.tobias@unchelath.unc.edu>; Cox, Lee <<u>lee.cox@dhhs.nc.gov</u>>; Nichols, Paula <<u>paula.nichols@dhhs.nc.gov</u>>

Cc: Yakaboski, Greg <<u>greg.yakaboski@dhhs.nc.gov</u>>

Subject: 3262 Nash Nash General Hospital 933368 Exemption

FYI...

Martha Waller

Administrative Specialist 1

Division of Health Service Regulation, Certificate of Need Section North Carolina Department of Health and Human Services

Main: 919-855-3873 Office: 919-855-3885

martha.waller@dhhs.nc.gov

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

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⁻⁻⁻⁻ Confidentiality Notice ----



2460 Curtis Ellis Drive, Rocky Mount, NC 27804 252 962-8000 / www.nashu3nchealthcare.org

April 14, 2020

Via E-MAIL

Greg Yakaboski, Project Analyst, Certificate of Need N.C. Department of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603

RE: Nash UNC Health Care

Replacement of Existing CT Scanner

Seeking CON Exemption NCGS 131E-184(a)(7) Rocky Mount, NC (FID 933368; Nash County)

Dear Mr. Yakaboski,

Nash Health Care Systems (d.b.a. "Nash UNC Health Care", "Nash UNC") seeks to replace an existing CT scanner with a new Rev HDe6 ES CT scanner from GE Healthcare, and locate it at Nash UNC's Emergency Department located at 2460 Curtis Ellis Drive, Rocky Mount, NC 27804, which is part of Nash UNC's main campus. The existing scanner will be sold or disposed of when the new scanner is operational.

The purpose of this letter is to provide the Agency with notice and to request a determination that the purchase of the replacement CT scanner is exempt from Certificate of Need ("CON") review because it is consistent with the replacement equipment definition outlined in N.C. Gen. Stat. 131E-176(22a) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements. Additionally, the project costs less than two million dollars and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

Pursuant to 10A N.C.A.C.14C.0303 the proposed CT scanner meets the replacement equipment definition because:

- 1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to technological improvements.
- 2. It is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service.
- 3. The acquisition of the proposed CT scanner will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- 4. The existing equipment was not purchased second-hand nor was the existing equipment leased.
- 5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

The costs related to the replacement totals \$760,163.98. Included in the total is: \$736,670.98, the new equipment cost, per Attachment A – Vendor Equipment Quote; \$23,493, the cost of minor renovations

needed to accommodate the installation of the new CT scanner, per Attachment B – Estimated Quote of Minor Renovations. This does not take into account the re-sale value of the existing CT scanner, which was being sourced prior to the COVID-19 outbreak, but has been deprioritized for now.

In support of our request, please find attached:

- Attachment A Vendor Equipment Quote
- Attachment B Estimated Quote of Minor Renovations
- Attachment C Equipment Comparison Chart

Nash UNC hereby requests that the Agency provide a written response confirming that the purchase of a replacement CT Scanner for the hospital space described herein does not require CON review. If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this request.

Sincerely,

Dorsey Tobias
Executive Director, Marketing, Communications & Strategy
Nash UNC Health Care

Enclosures

Nash General Hospital, Nash Day Hospital, Coastal Plain Hospital, and Bryant T. Aldridge Rehabilitation Center