



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

May 16, 2019

Amber W. George
5029 Falls of Neuse Road, Suite 210
Raleigh, NC 27609

Exempt from Review – Replacement Equipment

Record #: 2938
Facility Name: Raleigh Radiology Clayton
FID #: 150392
Business Name: Pinnacle Health Services of North Carolina, LLC
Business #: 1432
Project Description: Replace existing mammography equipment
County: Johnston

Dear Ms. George:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letters of May 7 and May 14, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the 3D Tomosynthesis Dimensions Mammography unit to replace the 2D Selena Digital Mammography unit. 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.

Moreover, you need to contact the Agency’s Construction and Radiation Protection Sections to determine if they have any requirements for development of the proposed project.

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,

Bernetta Thorne-Williams
Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Williams, Bernetta

From: Amber George <ageorge@oiarad.com>
Sent: Tuesday, May 14, 2019 2:09 PM
To: Williams, Bernetta
Subject: [External] PHS-Raleigh Rad Clayton

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov<<mailto:report.spam@nc.gov>>

Good afternoon Bernetta,

Thank you for reaching out today seeking clarification regarding our request to remove and replace the mammography equipment in the Clayton location.

This is to confirm our intention to decommission and trade in the existing 2D Selena Digital Mammography unit and replace it with the Tomosynthesis Dimensions mammography unit.

The best physical address for correspondence for me is:

5029 Falls of Neuse Rd. Ste 210
Raleigh, NC 27609

Thank you,
Amber George
Administrator
Raleigh Radiology

Sent from my iPhone

This email contains CONFIDENTIAL INFORMATION which may include protected health information and is legally privileged. This information is intended only for the use of the addressee named above. If you are not the intended recipient of this email or the employee/agent responsible for delivery to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of this email may be strictly prohibited. If you received this email in error please notify the sender immediately.

This message was secured by Zix(R).

FID# 150392
Record# 2938



May 7, 2019

Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination for Acquisition of Replacement Diagnostic Imaging Equipment at Raleigh Radiology Clayton/Clayton, Johnston County

Dear Ms. Frisone:

Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Clayton (RRC), intends to replace certain medical diagnostic equipment at its imaging center located at 166 Springbrook Avenue in Clayton. RRC requests a determination that acquisition and operation of this replacement equipment at this location does not constitute the development of a "diagnostic center" pursuant to NCGS 131E-176(7)(a) and will not otherwise be subject to certificate of need (CON) review.

RRC has been in operation since 2007, and at its current location since 2012. Currently RRC offers general x-ray, bone density, ultrasound, mammography, and MRI (via a mobile MRI) imaging services. RRC plans to remove the existing 2D mammography system from RRC and install a new 3D mammography (digital breast tomosynthesis or DBT) system. 68% of mammography patients at other RR locations are choosing this enhanced technology. As shown on the attached vendor quotation, the DBT system costs \$195,000 (plus applicable 6.75% sales tax of \$13,163 and rigging/installation costs of \$3,000). Thus, the total combined cost of the replacement medical diagnostic equipment is \$211,163 (\$195,000 + \$13,163 + \$3,000), including sales tax.

RRC is planning to install the DBT system within the existing RRC spaces. Please see the attached floorplan portraying the existing RRC imaging center, including the mammography room. The only facility modification required to accommodate the DBT system is a 40-amp breaker installation, which has an estimated cost of \$1,615.

Please see the attached list of existing medical diagnostic equipment (costs exceeding \$10,000) at RRC. As the table shows, following replacement of the 2D mammography system with the DBT system, the total cost of the medical diagnostic equipment at RRC will be \$441,408. NCGS 131E-176(7)(a) states "*Diagnostic center*" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the 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.

Based on the information provided in this letter, RRC requests a determination from the Division of Health Service Regulation that the acquisition and operation of this replacement medical diagnostic equipment at RRC will not constitute development of a "diagnostic center" pursuant to NCGS 131E-176(7)(a) and will not otherwise be subject to CON review.

I appreciate your attention to this matter. Please contact me at 919.877.5428 regarding any questions concerning this request.

Sincerely,

Amber W. George, CRA, RT-R (M)

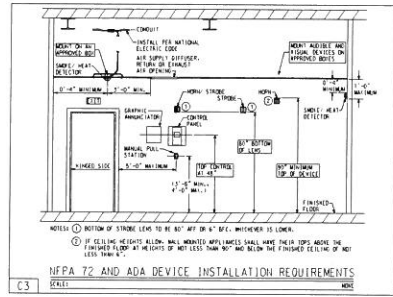
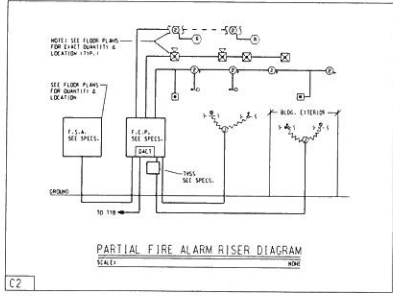
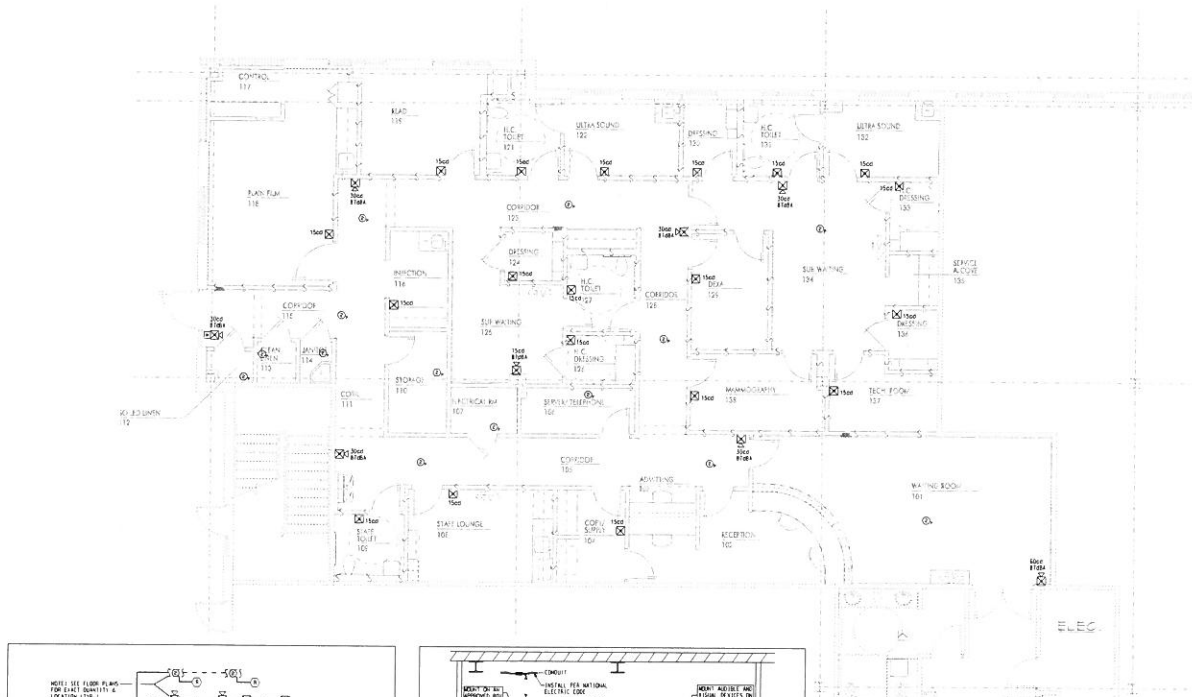
Amber George
Administrator
Outpatient Imaging Affiliates

Attachments: RRC Diagnostic Medical Equipment Inventory
Vendor Quotation
Architect Line Drawing

Raleigh Radiology Clayton Medical Diagnostic Equipment Inventory

<i>Serial #</i>	<i>Equipment Type</i>	<i>Initial Cost, including tax</i>	<i>Condition</i>	<i>Date Acquired</i>	<i>Manufacture Date</i>	<i>Useful Life</i>
04574M210D	Ultrasound system	\$ 61,915	fair	4/27/2010	2010	7
17063382	Ultrasound table	\$ 8,129	excellent	6/1/2017	2017	10
165577SU8	Ultrasound system	\$ 70,015	good	3/13/2012	2011	7
14072862	Ultrasound table	\$ 8,124	excellent	7/22/2014	2014	10
28407071989RM	2D digital mammography system	\$ 165,463	good	4/3/2012	2012	7
	CAD license	Included				7
06760288	Digital radiography film reader	\$ 15,799	fair	8/27/2012	2006	7
10797501-L	Digital radiography system	\$ 41,810	fair	10/1/2012	2002	7
10220	Bone Densitometer	\$ 22,839	fair	10/2/2012	1999	7
	Current RRC total	\$ 394,093				

RRC total less 2D mammo	\$ 228,630
replacement DBT system	\$ 208,163
rigging/installation	\$ 3,000
40-amp breaker install	\$ 1,615
New RRC total with DBT system	\$ 441,408



WALL LEGEND

---	EXISTING WALL TO REMAIN
---	NEW ONE HOUR SHUNT WALL
---	NEW ONE HOUR FIRE RATED METAL STUD CYP. BOARD WALL
---	NEW NON-RATED METAL STUD CYP. BOARD WALL
---	SOUND WALLS

FIRE ALARM FLOOR PLAN
 SCALE: 1/4" = 1'-0"
 3,895 NET SQUARE FEET

GENERAL NOTES:
 1. VERIFY ALL FIRE ALARM DEVICES INTO EXISTING BUILDING FIRE ALARM SYSTEM WHEN EXISTING FIRE ALARM SYSTEM AND DEVICES.

C2

C3

From: [Amber George](#)
To: [David Meyer](#)
Subject: FW: DOTmed Listing #2621879 Digital Mammo Unit, DIMENSION 2D/3D by HOLOGIC
Date: Tuesday, May 7, 2019 9:11:00 AM
Attachments: [image001.png](#)
[image002.png](#)
[image004.png](#)

David,
Below is quote/FMV #2 for a DBT mammo system

Amber W. George, CRA, RT-R (M)
Administrator
Raleigh Radiology

Office: 919-877-5428
Cell: 919-332-3695



State Of The Art Everything. Straight From The Heart Care.

From: Kelly Firestine <kfirestine@oiarad.com>
Sent: Tuesday, May 7, 2019 9:09 AM
To: Amber George <ageorge@oiarad.com>
Subject: FW: DOTmed Listing #2621879 Digital Mammo Unit, DIMENSION 2D/3D by HOLOGIC

Thank you,

Kelly Firestine BSRT(R)(CT)(M), CRA, CHC, CPCO, MRSO
Senior Director of Operations
840 Crescent Centre Drive, Suite 200
Franklin, TN 37067
Office: (615) 523-4285 Mobile: (615)720-0914



From: John Pereira <john@unitedmedicaltech.com>

Sent: Tuesday, April 16, 2019 6:21 AM

To: Kelly Firestine <kfirestine@ojarad.com>

Subject: RE: DOTmed Listing #2621879 Digital Mammo Unit, DIMENSION 2D/3D by HOLOGIC

External Email Disclaimer

WARNING: This email originated outside of OIA. DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

Hi Kelley,

We have this DIMENSIONS 3D available now in our warehouse. The price is \$195,000. Ex-Fort Myers, warehouse. Buyer can come to see and inspect this system in our warehouse prior to purchase. Shipping, installation or any warranty is not included in the price. This offer is subject to prior sale. As an alternative we also have a 2014 GE SenoClaire 3D TOMO for only \$125,000. Or \$175,000. Delivered, installed and a 3 month warranty is included. Please e-mail or call me with any questions at 239 433 5332 or mobile 239 470 5168

John Pereira at United Medical
2196 Andrea Lane,
Fort Myers, Florida 33912. USA
Phone: 239-433-5332, Fax: 239-433-3919
john@unitedmedicaltech.com
www.radiology-equipment.com



United Medical Technologies Corp.
Diagnostic Imaging Equipment

This email contains CONFIDENTIAL INFORMATION which may include protected health information and is legally privileged. This information is intended only for the use of the addressee named above. If you are not the intended recipient of this email or the employee/agent responsible for delivery to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of this email may be strictly prohibited. If you received this email in error please notify the sender immediately.