



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

VIA EMAIL ONLY

August 31, 2021

Gary S. Qualls
Gary.Qualls@klgates.com

No Review

Record #: 3655
Date of Request: July 23, 2021
Facility Name: Charlotte Radiology SouthPark Breast Center
FID #: 021188
Business Name: Charlotte Radiology, P.A.
Business #: 468
Project Description: Replace existing mammography unit
County: Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described 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.

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,

Julie M. Faenza

Micheala Mitchell
Chief

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

July 23, 2021

Via E-Mail

Lisa Pittman, Assistant Chief
Julie Faenza, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: No Review Request Regarding Replacement Mammography Unit at Charlotte Radiology SouthPark Breast Center (a Diagnostic Center)

Dear Ms. Pittman and Ms. Faenza:

We are filing this No Review Request on behalf of our client, Charlotte Radiology, P.A., (“CR”) with the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”). CR’s SouthPark Breast Center has been recognized as a diagnostic center under the North Carolina Certificate of Need (“CON”) Law since 2007 (the “CR SouthPark Breast Center”). See Exhibit 1 (a copy of the 2007 CON).

The 2007 CON reflects the location’s name as Charlotte Radiology Morrocroft Breast Center, because the CON originally approved the diagnostic center for 6836 Morrison Boulevard, Suite 100, Charlotte, 28111. See Exhibit 1. The CR SouthPark Breast Center later relocated approximately 0.3 miles away for less than \$200,000 and is now located at 4525 Cameron Valley Parkway 1000-A, Charlotte, NC 28211. No CON was required for that relocation since: (1) the costs associated with the relocation did not exceed \$2 Million; and (2) the diagnostic center remained in the same service area. See N.C. Gen. Stat. § 131E-176(16)(b) and (q).¹

¹ CR’s counsel discussed with Martha Frisone whether CR should make any letter filing related to the diagnostic center relocation. Ms. Frisone apprised counsel that such a filing was not necessary.

Lisa Pittman, Assistant Chief
Julie Faenza, Project Analyst
July 23, 2021
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CR files this No Review Request to obtain verification that its proposed CR SouthPark replacement mammography (the "Replacement Mammo Unit") at the SouthPark Breast Center diagnostic center is not reviewable. Exhibit 2 to this letter is a quote from HOLOGIC for the Replacement Mammo Unit. As Exhibit 2, page 2 illustrates, the cost to acquire the Replacement Mammo Unit is \$279,833.84. The existing mammography unit being replaced is a HOLOGIC Selenia System, which is currently operational at the site (the "Existing Mammo Unit").

The quote in Exhibit 2 includes the costs to remove the Existing Mammo Unit and install the Replacement Mammo Unit. The Replacement Mammo Unit quote shows a \$40,000 trade-in credit for the Existing Mammo Unit, which we are adding back to the equipment cost for CON threshold calculation purposes. Thus, the total cost related to acquiring and making operational the Replacement Mammo Unit is \$319,906 = (\$279,833.84 + \$40,000). Moreover, there are no renovation costs or other upfitting costs.

The CON Law regulates equipment acquisitions as "major medical equipment" only if the relevant costs exceed \$750,000. The statutory definition of major medical equipment in N.C. Gen. Stat. § 131E-176(14o) reads 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 fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred 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.

N.C. Gen. Stat. § 131E-176(14o).

Thus, given that the total relevant costs for the Replacement Mammo Unit are \$319,906, the proposed Replacement Mammo Unit does not meet the above-cited definition of "major medical equipment" given that those costs are under \$750,000. Because the Replacement Mammo Unit would not be reviewable as major medical equipment in the first instance (and thus not reviewable as a new institutional health service under N.C. Gen. Stat. § 131E-176(16)), we need not discuss the replacement equipment exemption provisions in N.C. Gen. Stat. § 131E-184, which are triggered only when a new institutional health service requires an exemption.

Lisa Pittman, Assistant Chief
Julie Faenza, Project Analyst
July 23, 2021
Page 3

In light of the foregoing, CR requests an Agency determination that its proposed Replacement Mammo Unit at the CR SouthPark Breast Center diagnostic center is not CON reviewable. Thank you for your assistance in regard to this matter. If you have any questions or need further information, please feel free to contact me at the number above.

Sincerely,



Gary S. Qualls

Lisa Pittman, Assistant Chief
Julie Faenza, Project Analyst
July 23, 2021
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Exhibits

1. Copy of the 2007 CON
2. Equipment Price Quote for the HOLOGIC Replacement Mammo Unit.

Exhibit 1

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED
for
Project Identification Number F-7736-06
FID#021188

ISSUED TO: Charlotte Radiology, P.A.
1701 East Boulevard
Charlotte, NC 28203

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Charlotte Radiology shall acquire digital mammography equipment to replace an existing analog mamnography unit and establish a diagnostic center at Charlotte Radiology Morrocroft Breast Center/Mecklenburg County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Charlotte Radiology Morrocroft Breast Center
6836 Morrison Boulevard
Suite 100
Charlotte, NC 28111

MAXIMUM CAPITAL EXPENDITURE: \$585,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: December 31, 2007

This certificate is effective as of the 20th day of September, 2007.

Greg B. Hoffman
Chief, Certificate of Need Section
Division of Health Service Regulation

Conditions

1. Charlotte Radiology, P.A. d/b/a Charlotte Radiology Morrocroft Center shall materially comply with all representations made in the certificate of need application and the supplemental documents provided to the Agency on September 12, 2007. In those instances in which any of these representations conflict, Charlotte Radiology, P.A. d/b/a Charlotte Radiology Morrocroft Center shall materially comply with the last-made representations.

2. Charlotte Radiology, P.A. d/b/a Charlotte Radiology Morrocroft Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.

3. Charlotte Radiology, P.A. d/b/a Charlotte Radiology Morrocroft Center shall remove and dispose of by sale or trade-in to another unrelated party, the existing mammography unit, upon installation of the replacement equipment.

Timetable

Ordering of equipment.....	September 24, 2007
Arrival of equipment.....	October 1, 2007
Operation of equipment.....	November 1, 2007
Offering of service.....	November 1, 2007

Exhibit 2



Purchase Quotation

PLEASE REFER TO THIS NUMBER ON ALL CORRESPONDENCES AND ORDERS

Quote #: Q-239893

Status: Approved

Quote Expiration Date: 7/30/2021

TO:

CUSTOMER NAME	CUSTOMER NUMBER
CHARLOTTE RADIOLOGY	82503
BILL TO ADDRESS	SHIP TO ADDRESS
700 E MOREHEAD ST STE 300 CHARLOTTE NC US 28202	4524 CAMERON VALLEY PKWY STE 1000 CHARLOTTE NC US 28211

TAX INFO:

Hologic is required by law to collect all state and local taxes on all sales. If an exemption certificate is not provided by customer at time of order, final invoices will include these amounts. Many states require both specific operator qualifications and/or licensing and registration of x-ray devices. Hologic is not responsible for fulfilling customer's regulatory obligations.



This Quotation is based on the information known by Hologic regarding your needs as of the date the Quotation is generated. This offer is subject to change or withdrawal by Hologic prior to acceptance. This Quotation and the governing terms as noted herein shall supersede all other quotations, agreements, understandings, warranties and representations, whether written or oral, between us, and may be accepted only in accord with their terms. In the event of a conflict between this Quotation and the governing terms, this Quotation shall prevail. To accept, please sign below within the time period for acceptance. Signed quote and/or purchase order should be forwarded by mail, via e-mail or by fax to:

Breast Health:
HOLOGIC, INC.
250 Campus Drive
Marlborough, MA 01752
ATTN: Sales Administration
Fax: (203) 731-8463
BSHSalesSupportUS@hologic.com

ATTN: Robert Neilon **Phone:** 704-612-4952 **Fax:** **Email:** robert.neilon@charlotteradiology.com

Quote Date	Hologic Representative	Estimated Delivery Date	Quote Currency
5/20/2021	Tracy Allen tracy.allen@hologic.com	8/16/2021	USD

Summary of Governing Terms/Contracts	Contract Number	FOB	Payment Terms	Freight Terms
Hologic Std T&C*		ORIGIN	45 NET	NO CHARGE
VIZIENT (XR0653) - MAMMO	XR0653	ORIGIN	45 NET	NO CHARGE

*For the purpose of clarity, the Products as contained herein that are not subject to a governing terms / contract as listed above, shall be governed by the applicable Hologic Terms and Conditions available at: <https://www.hologic.com/hologic-sales-terms-conditions>

Replacement Unit for SouthPark

Qty	Product Name	Description	List Price	Unit Price	Extended Price
1	SDA-SYS-3000-3D	SELENIA® DIMENSIONS® 3D™ PERFORMANCE SYSTEM	\$643,000.00	\$285,215.00	\$285,215.00
1	ASY-10935	3D KIT MAMMOPAD ACCESSORY	Included	Included	Included
1	PRD-04420	HIGH RESOLUTION READY DETECTOR	Included	Included	Included
1	PRD-04749	KIT, NON-TOUCH SCREEN CONTROL MONITOR, UNIVERSAL ERGO AWS	Included	Included	Included
1	DIM-DISP-2MP	SDM; 2MP DISPLAY OPTION	\$4,650.00	\$2,883.00	\$2,883.00

Quote #: Q-239893-1

Qty	Product Name	Description	List Price	Unit Price	Extended Price
1	FAB-12469	SHIELD, UNIVERSAL AWS	Included	Included	Included
1	ASY-10994	KIT, FIXED MONITOR MOUNT, 2MP COLOR MONITOR, UNIVERSAL ERGO AWS	\$1,600.00	\$1,152.00	\$1,152.00
1	SDM-LIC-0005	C-VIEW SOFTWARE LICENSE	\$40,000.00	\$20,000.00	\$20,000.00
3	ASY-04662	RACK, PADDLE STORAGE	\$400.00	\$250.00	\$750.00
1	ASY-04194	KIT, DIAGNOSTIC PADDLES	\$4,000.00	\$2,000.00	\$2,000.00
1	SVC-SDM-OPT-BTO	SELENIA DIMENSIONS BTO ENABLED	Included	Included	Included
1	SDM-TRAIN-INIT-03	MEDICAL PHYSICIST, DIMENSIONS, INITIAL TRAINING, 8 HRS (5 HRS LIVE - 3 HRS ONLINE TRAINING), 1 SITE, MAX 2 PHYSICISTS	Included	Included	Included
1	SDM-TRAIN-INIT-04	RADIOLOGISTS, TOMOSYNTHESIS, INITIAL TRAINING, 8 HOURS VIRTUAL TRAINING, 14 RADIOLOGISTS	Included	Included	Included
1	TRADE-HOLX_SDM3D	TRADE-IN OF HOLOGIC SELENIA DIMENSIONS 3D SYSTEM (INSTALLED AND FUNCTIONING)	Included	\$-40,000.00	-\$40,000.00
1	DIM-LIC-IC-XFR	IMAGE CHECKER CAD 10.0 LICENSE TRANSFER FROM CENOVA SERVER TO AWS. AWS SW 1.10/2.1 REQUIRED.	Included	\$0.00	Included
1	ASY-08446	KIT, UPS, UNIVERSAL AWS	\$3,500.00	\$2,380.00	\$2,380.00
1	BSH-VOLUME-DISCOUNT	BSH PORTFOLIO VOLUME DISCOUNT	Included	\$-19,453.35	-\$19,453.35
Replacement Unit for SouthPark TOTAL:					\$254,926.65

Add on Needle Loc Kits

Qty	Product Name	Description	List Price	Unit Price	Extended Price
2	DIM-KIT-NLOC	DIMENSIONS NEEDLE LOCALIZATION KIT	\$10,000.00	\$1,762.50	\$3,525.00
Add on Needle Loc Kits TOTAL:					\$3,525.00

*To the extent this Quotation contains any Professional Services for Equipment relocation or clinical training, such Professional Services shall be governed by the Hologic Professional Services Terms and Conditions (US Customers), available at <https://www.hologic.com/hologic-master-sales-terms-conditions>. To the extent this Quotation contains any Products with Product Name UA-SUB-SW-0001, UA-SW-002, UEQ-SUB, DIM-LIC-QT-SUB (collectively "Subscription Products"), such Subscription Products shall be governed by the Hologic Subscription Terms and Conditions US, available at available at <https://www.hologic.com/hologic-master-sales-terms-conditions>, and the Effective Term for said Subscription Products shall be a twelve (12) month period beginning on the date of designated Equipment for such Subscription Software. Otherwise, any Products with Governing Terms listed as "Hologic Std T&C" shall be governed by the Hologic Sales Terms and Conditions US, available at <https://www.hologic.com/hologic-master-sales-terms-conditions>.

List Price Total: USD 717,950.00
Discount: USD 459,498.35
Total Quote Price: USD 258,451.65
Tax: USD 21,382.19
Final Quote Price: USD 279,833.84

Replacement Unit for SouthPark

Upgrade	Serial Number
DIM-LIC-IC-XFR	

Customer agrees to keep the discount price provided to them in this quote or agreement confidential and not disclose it to anyone other than as required by law or court order.

Title Transfer

The undersigned CHARLOTTE RADIOLOGY ("Transferor"), for valuable consideration hereby transfer title for property defined as:

Replacement Unit for SouthPark

Product Name	Trade-In Manufacturer	Trade-In Serial #
TRADE-HOLX_SDM3D	Hologic	81012144177

to Hologic, Inc. of 250 Campus Drive, Marlborough, MA 01752, effective as of date of the actual pick-up of the property by Hologic, Inc.

If applicable, Transferor acknowledges as such consideration a trade-in credit value of

US \$ _____ (if known) toward purchase of a Hologic Model _____

Transferor warrants in regard to the property being transferred that:

1. Transferor is the legal owner,
2. Transferor will defend the title against any and all claims and demands of all persons,
3. Transferor will take all further steps necessary to effectively transfer ownership to Hologic, Inc., at no cost or expense to Hologic, Inc., and
4. It is free from all liens and encumbrances
5. All patient data stored within the hard drive(s) of transferred property has been removed from all data storage devices in accordance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health of 2009 ("HITECH") regulations implemented by the U.S Dept. of Health and Human Services.
6. The transferred property has been thoroughly cleaned and, if property has been in contact with potentially infectious materials (blood, blood products or other potentially infectious materials), it must be decontaminated in accordance with OSHA 29 CFR 1910.1030 "Bloodborne Pathogens." If it is not feasible to fully decontaminate the equipment, the equipment must be clearly labeled with a warning sign that indicates the possible presence of blood/body fluids. Decontamination must be done with an appropriate EPA approved disinfectant - <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>).

If Transferor and Hologic are parties to a Service Agreement providing maintenance and repair services for the property being transferred herein, then this Title Transfer shall serve as an amendment to said Service Agreement terminating coverage with respect to the transferred property. The termination of coverage shall be effective as of the date of the actual pick-up of the property by Hologic, Inc.

To HAVE AND TO HOLD the same, with the rights, privileges, and appurtenances thereof, unto Hologic, Inc., its successors and assigns, forever, to its own use and behalf.

This agreement will be construed in accordance with and governed by the laws of the state of Massachusetts.

Hologic may request new customers and established customers to complete our credit application to create or update current credit files. This requirement will be contingent on order amount and prior history with Hologic.

Unless otherwise agreed in writing or specified herein, the Parties will schedule delivery of Products within one year of Quote Expiration Date.

The parties acknowledge that they intend for purchases under this Quote to be reported to the identified group purchasing organization ("Identified GPO") for payment of administrative fees in accordance with the applicable group purchasing organization contract between the identified GPO and Hologic. This Quote is not entered into, pursuant to, or in connection with any other group purchasing or IDN/System, arrangement of which Customer or Hologic is a party, and is not intended to result in the reporting of sales or the payment of administrative fees to any such organization other than the identified GPO.

The Customer agrees to treat all quoted and sales information as confidential and not to disclose it to any third party other than the identified GPO or as required by law.

In no event will Hologic be obligated to pay administrative fees to a group purchasing organization ("GPO"), integrated delivery network, or other entity other than the identified GPO with respect to any single purchase order by Customer, and whose Equipment and purchase options are not included in the separate GPO agreement between the identified GPO and Hologic.

Customer acknowledges that the pricing guaranteed under this Quote is strictly provided to Customer only because the pricing is based on the Customer's commitment related to quantity and commitment to Hologic products, and in no event shall Hologic be required to offer such pricing to any other customer who is in anyway affiliated with or is a member of the identified GPO.

If purchasing under a buying group with existing terms and conditions, those conditions would supersede Hologic's standard terms and conditions. If a buying group does not have their own terms and conditions, Hologic's would apply.

Buyer Acceptance

CHARLOTTE RADIOLOGY

By: _____ (signature)

Name: _____ Title: _____ (print/type)

Date: _____

Additional Buyer Acceptance (if applicable)

By: _____ (signature)

Name and Title: _____ (print/type)

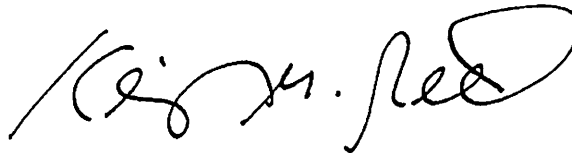
Date: _____

Please provide the Shipping and Billing address here if different from the quote address above
(If this section is left blank, the product will ship and bill to the addresses printed at the top)

Shipping Address

Billing Address:

Hologic Approval:



Date:

HOLOGIC, INC. 250 CAMPUS DRIVE. MARLBOROUGH MA 01752

Product Name	Long Description
SDA-SYS-3000-3D	<p>Hologic Selenia® Dimensions® 3000 system for Genius® 3D Mammography™ screening and diagnostic imaging. Upgradable to interventional or mobile imaging. INCLUDES:</p> <p>X-ray Gantry:</p> <ul style="list-style-type: none"> · Generator: Fully integrated constant potential, high frequency, inverter type. · Detector: High-resolution ready detector. · X-ray Tube: Tungsten, bi-angular, high speed, high heat capacity. · X-ray Filters: Rhodium, silver, aluminum. · Anti-scatter Grid: Auto-retracting linear grid. <p>Fixed-height Acquisition Workstation:</p> <ul style="list-style-type: none"> · CPU: Standard computer, multi-core Intel-based CPU, minimum 16 GB RAM, minimum 2 TB disk, Windows 10/64, NVIDIA GPU. · Includes DVD +/- R/W. · User Interface: 1.2 MP color LCD control monitor. Full X-ray shield, pull-out keyboard drawer, keyboard and mouse. <p>Selenia Dimensions Software:</p> <ul style="list-style-type: none"> · User access control, patient and study selection, imaging procedure selection and definition, X-ray parameter control, image review and acceptance/rejection, quality control. · Licenses: Tomosynthesis imaging, Diagnostic Imaging, Dynamic Tube Head Motion. <p>Connectivity:</p> <ul style="list-style-type: none"> · DICOM: Modality work list, storage, storage commitment, query/retrieve, print. · IHE Profiles: Scheduled workflow, patient information reconciliation, mammography image. · Advanced Connectivity: Ability for the system to participate in DICOM Modality Performed Procedure Step (MPPS) transactions and to output DICOM Radiation Dose Structured Report (RDSR) objects to third-party dose aggregation and reporting systems. The MPPS and RDSR capabilities can be enabled and disabled independently. <p>Accessories:</p> <ul style="list-style-type: none"> · Screening Paddles (3): 24 x 29 cm, 18 x 24 cm, small breast. · Other Paddles (3): 10 cm contact, 10 cm magnification, 7.5 cm spot contact for use during QC testing only. · Other: Magnification stand with mag platform, flat field phantom and case, ACR tomosynthesis geometry calibration phantom, Dimensions interconnect cable kit, 2D fixed face shield, retractable 3DMammography™ face shield, User, service, maintenance, and QC manuals. MammoPad® Breast Cushion trial box. Quote #: Q-239893-1 <p>· Hologic Platinum Marketplace: Page 8 of 10 Co-operative marketing program focused on business growth through patient and referring physician education. Complete initiation form at hologicmarketplace.com/user/register. Estimated</p>

Product Name	Long Description
PRD-04420	<p>Hologic 3D Mammography™ high-resolution ready digital image receptor for 3Dimensions™ mammography systems or Selenia® Dimensions® systems.</p> <p>INCLUDES:</p> <p>Digital Image Receptor</p> <ul style="list-style-type: none"> •Amorphous selenium, TFT •Structure: Single 24 x 29 cm plate •Image Matrix Sizes: 2560 x 3328 (18 x 24 cm); 3328 x 4096 (24 x 29 cm) •Pixel Size: 0.070 mm •Limiting Spatial Resolution: 7.1 lp/mm. <p>(Hologic Clarity HD license purchase required to enable Clarity HD high-resolution imaging on 3D Performance and Dimensions 6000 and 9000 systems. This license is included with a 3Dimensions system.)</p>
PRD-04749	A 17" flat panel color monitor available on the Selenia Dimensions Avia 3000 and 6000 packages (1280X1024 viewing area, 56-76HZ).
DIM-DISP-2MP	Selenia Dimensions 2MP Display Option. Includes: • 21.3" clinical display monitor for hospital wide-viewing of clinical data and images, with 1600x1200 maximum resolution tft am color, active display 432hx324mm(17x12.8), lcd 2mp, 100/240v, 5a 50/60
FAB-12469	SHIELD, UNIVERSAL AWS
ASY-10994	Provides all mounting hardware and cabling necessary for mounting a 2MP Color Monitor onto a fixed pole on the Selenia Dimensions system Avia 3000, 6000 and 9000 packages. Monitor sold separately.
SDM-LIC-0005	Enables creation of C-View™ generated 2D images on Selenia® Dimensions® systems or 3Dimensions™ systems configured with Hologic standard resolution 3D™ imaging. The C-View software license adds the ability to create low dose tomosynthesis studies in Tomo HD (standard tomo + C-View) and Combo HD (standard tomo + FFDM + C-View) imaging modes. Includes: •C-View Generated 2D Imaging software license
ASY-04662	Wall-mounted, felt-lined rack for storing system compression paddles. Each rack, sold separately, provides enough storage room for 3-4 compression paddles. Includes: •Paddle storage rack with felt lining •Wall-mounting bracket (installation not included) •Graphic paddle labels Dimensions: •W x H x D: 36 1/4" x 7" x 4" (from the wall) •Minimum Vertical Pitch: 12" to 14" when multiple racks are installed one above another Recommended: •Selenia® Dimension® Avia systems: min. 1 rack •Selenia Dimensions 2D systems: min. 2 racks •Selenia Dimensions 3D™ systems: min. 3 racks •3Dimensions™ systems: min. 3 racks Requirements: •Must be securely attached to the wall •Must be installed by a professional installer
ASY-04194	The diagnostic paddle kit for Selenia® Dimensions®. Includes: frameless spot contact paddle (ASY-01950), 7.5cm spot contact paddle (ASY-01986), 7.5cm spot magnification paddle (ASY-02162).

Product Name	Long Description
SVC-SDM-OPT-BTO	This configuration enables output of tomosynthesis slices in DICOM Breast Tomosynthesis Image Object form. Use of this configuration will first require an integrated planning team, including your IT department, Hologic and other vendors, to work together to ensure that your enterprise is ready for use of the tomosynthesis data in DICOM Breast Tomosynthesis Image Object form. The completion of critical feasibility questions included in Hologic's Enterprise Survey will guide the team through understanding any infrastructure requirements and changes necessary. Note: While a preliminary check by your Hologic representatives may have allowed the ability to quote this output configuration, completion of the Enterprise Survey is required before Dimensions Tomosynthesis system or option is enabled. Software and hardware upgrades may be required. Hologic makes no guarantees of software and hardware performance for products not associated to Hologic. By signing this quote, the customer agrees that the completion of purchase of the accompanying Hologic products shall not be contingent on the implementation of this no-charge configuration. Requires: - Completion of Hologic Enterprise Survey by site personnel in conjunction with Hologic representatives - PACS system including Deep Archive capable of storing / retrieving DICOM Breast Tomosynthesis Image Objects and with suitable storage capacity - Softcopy review workstation capable of displaying DICOM Breast Tomosynthesis Image Objects
SDM-TRAIN-INIT-03	Medical physicists training for a new mammography system. Included in in the purchase price of your system are (8) hours of Hologic tomosynthesis educational training for up to (2) physicists. Initial training is included in the purchase price of your system/license and is valued at \$1,500 (unused training cannot be deducted from your purchase price). Five (5) hours of live tomosynthesis training for up to 2 medical physicists with a Hologic Field Service Engineer during the installation of the system and access to Hologic's 3-hour online tomosynthesis training course for medical physicists to fulfill the 8-hour FDA requirement. See course description for more details and requirements. Visit www.hologic.com/training for a complete list of Hologic educational opportunities. Please note: Cancellation must be made 6 business days prior to the confirmed and scheduled training start date. Fee for cancellation within 6 business days of confirmed training is \$2,000.
SDM-TRAIN-INIT-04	Radiologist training for 3Dimensions™ or Selenia® Dimensions® system(s). Initial training is included in the purchase price of your system and is valued at \$5,250 (unused training cannot be deducted from your purchase price). Access to Hologic's virtual tomosynthesis training course for up to 14 radiologists. This program will fulfill the 8-hour FDA training requirement. See course description for more details and requirements. Visit www.hologic.com/training for a complete list of Hologic educational opportunities.
DIM-LIC-IC-XFR	Provides license transfer from one Cenova server to AWS. Allows an existing IMAGE CHECKER CAD 10.0 license to be migrated from one Cenova™ server to the AWS, preserving the investment in Image Analytics software products.
ASY-08446	Provides an Uninterruptible Power Supply module to help protect the computer subsystems in the Selenia Dimensions system Avia 3000, 6000 and 9000 packages. Supports organized shutdown should the acquisition workstation lose power.
BSH-VOLUME-DISCOUNT	1) Additional discount applied to customer purchasing multiple modalities (ex. Dimensions and Horizon products) across Hologic portfolio 2) Products being bundled must have line item value on quote 3) If bundled products are NOT on the same quote, the correlating quote or contract number must be referenced in the customer notes

Add on Needle Loc Kits

Product Name	Long Description
DIM-KIT-NLOC	Optional kit for needle localization procedures for 3Dimensions™ systems. Includes: crosshairs paddle, magnification crosshairs paddle, 10 cm open localization paddle, 10 cm open magnification localization paddle.

Faenza, Julie M

From: Faenza, Julie M
Sent: Wednesday, August 25, 2021 4:30 PM
To: Qualls, Gary
Subject: RE: [External] No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, an existing diagnostic center.

Gary, we have finally sorted this out and are processing the no review request. If you would be so kind as to pass this information on to Charlotte Radiology, please let them know that, for CON purposes, Morehead Breast Center and Project ID #F-6725-02 are now associated with FID #210687. Thanks again for your patience (and for your client's patience) and my apologies that sorting this out took so long.

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), [Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873 (*I am working remotely most of the time; email is the best way to reach me.*)

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

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From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, August 10, 2021 9:04 AM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Subject: RE: [External] No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, an existing diagnostic center.

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Thanks for the update

Gary

From: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Sent: Tuesday, August 10, 2021 8:59 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: RE: [External] No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, an existing diagnostic center.

Gary, I just wanted to follow up with you. We are still working on sorting out the inadvertent linking of the two separate diagnostic centers. The delay has nothing to do with what is in the request itself. I will keep working

on this until we get it fixed and get your response out ASAP. You are always welcome to inquire as to the status, of course, but I will also reach out and keep you posted. Let me know if you have any questions.

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), [Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873 (*I am working remotely most of the time; email is the best way to reach me.*)

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From: Qualls, Gary <Gary.Qualls@klgates.com>

Sent: Monday, August 2, 2021 11:49 AM

To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Subject: [External] No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, an existing diagnostic center.

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Julie:

On behalf of Charlotte Radiology ("CR"), please see our responses below to your questions.

Your Question #1:

First, can you confirm that the Morehead Breast Center and the Morrocroft Breast Center have always been two separate diagnostic centers?

Our Response to Your Question #1:

Yes, the Morehead Breast Center and Morrocroft (a/k/a SouthPark) Breast Center have always been two separate diagnostic centers.

Your Question #2:

Second, can you tell me whether anything at the Morrocroft Breast Center is subject to oversight from the Radiation Protection Section here at DHSR? If they have never been the same facility and they are not subject to oversight from Radiation Protection Section, then we'll issue a different FID# for Morrocroft. But we don't want to mess up anything if they are already being tracked in a system, and I don't know what kind of equipment is at that diagnostic center.

Our Response to Your Question #2:

CR's SouthPark Breast Center (a/k/a Morrocroft) equipment consists of three (3) mammography units, one of which we are seeking to replace through the pending No Review Request. CR's SouthPark Breast Center mammography units are subject to the Radiation Protection Section's oversight. We are not sure why CR's SouthPark Breast Center has the same FID number as CR's Morehead Breast Center.

Let us know if you have further questions.

Thanks

Gary

From: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Sent: Monday, July 26, 2021 4:33 PM

To: Qualls, Gary <Gary.Qualls@klgates.com>

Subject: RE: [External] No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, an existing diagnostic center.

Gary – I'm not sure why, but the CON for this project was issued with an FID# belonging to a different facility.

Based on my research, what I believe happened was a CON was issued for what is now Charlotte Radiology Morehead Breast Center to acquire an MRI and develop a diagnostic center. That CON (F-6725-02) was issued in September 2003 for the same site address that is listed on the CON for F-7736-06; however, it appears that Morehead Breast Center got a declaratory ruling in 2005 to develop the facility at a different location, and it was developed in 2005.

What I think happened next was the application for F-7736-06, at the same address listed originally for F-6725-02, but since the address was the same, the two CONs were linked via FID# (when they shouldn't have been).

What I'm trying to do is sort this out on our end so I can make sure our records are accurate and we are able to differentiate between the two facilities, so I need just a couple of pieces of information. First, can you confirm that the Morehead Breast Center and the Morrowcroft Breast Center have always been two separate diagnostic centers? Second, can you tell me whether anything at the Morrowcroft Breast Center is subject to oversight from the Radiation Protection Section here at DHSR? If they have never been the same facility and they are not subject to oversight from Radiation Protection Section, then we'll issue a different FID# for Morrowcroft. But we don't want to mess up anything if they are already being tracked in a system, and I don't know what kind of equipment is at that diagnostic center.

I'm attaching an administrative determination from last year that discusses F-6725-02 and the declaratory ruling to help fill in some of the story.

(There's no issue with the request itself. It's just that until I can get the issue sorted out about the facilities being linked, I can't finalize any response.)

Thanks Gary!

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section

NC Department of Health and Human Services

Office: 919-855-3873 (I am working remotely most of the time; email is the best way to reach me.)

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

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-----Original Message-----

From: Qualls, Gary <Gary.Qualls@klgates.com>

Sent: Friday, July 23, 2021 4:04 PM

To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>; Pittman, Lisa <lisa.pittman@dhhs.nc.gov>

Subject: [External] No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, an existing diagnostic center.

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Julie and Lisa:

Attached for filing is a No Review Request for a mammography equipment replacement at Charlotte Radiology's SouthPark Breast Center, which is an existing diagnostic center.

Please confirm receipt.

Thanks!

Gary

Gary S. Qualls
Partner
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Phone: 919-466-1182
Fax: 919-516-2072
gary.qualls@klgates.com

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