



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne, Director
Health Service Regulation

November 23, 2016

Mano Mahadeva,
Solis Mammography
15601 Dallas Pkwy., Suite 500
Addison, Texas 75001

No Review

Record #: 2099
Facility Name: Solis Mammography Greensboro
FID #: 160013
Business Name: Solis North Carolina Diagnostic Imaging & Breast Center Management, Inc.
Business #: 2336
Project Description: Replace existing mammography equipment
County: Guilford

Dear Mr. Mahadeva:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter on November 22, 2016, 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 your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that 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.

However, you need to contact the Agency's Radiation Protection Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704


An Equal Opportunity/ Affirmative Action Employer




Mr. Mahadeva
November 23, 2016
Page 2

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,


Celia C. Inman
Project Analyst


Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

S LIS

Mammography

Ms. Martha Frisone
Assistant Chief
Health Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704



RE: Solis North Carolina Diagnostic Imaging & Breast Cancer Management, Inc.
Facility: Solis Mammography – Greensboro
County: Guilford
FID #: 160013

Dear Ms. Frisone,

Solis North Carolina Diagnostic Imaging & Breast Center Management, Inc. ("Solis Mammography") intends to replace its existing Hologic Mammography Selenia Tungsten (2D) (model ASY-01427) with a used Hologic 3D Selenia Dimensions (3D) unit at its existing Diagnostic Center located at 1126 N. Church Street, Suite 200 in Greensboro North Carolina. Solis Mammography obtained CON approval on April 29, 2016 to be designated as a Diagnostic Center in accordance with the representations in the CON Project I.D. # G-11118-16.

The replacement equipment proposed to be acquired by Solis Mammography has the same technology as the equipment currently in use. Although the replacement equipment will possess expanded 3D capabilities due to technological improvements, the replacement equipment will be functionally similar to the equipment being replaced and will be used for the same diagnostic and/or treatment purposes as the equipment currently in use.

The replacement equipment will not be capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment. The replacement equipment will not be used to provide a new health service.

The replacement equipment to be acquired is reconditioned (refurbished) equipment. The existing equipment was new when purchased. The replacement equipment will be purchased more than three years after the acquisition of the existing equipment. The existing equipment is owned, not leased, by Solis. The purchase cost of the used replacement Hologic 3D Selenia Dimensions (3D) unit will be \$318,000 which will increase depreciation costs to the facility by less than 5 percent per procedure. The acquisition of the replacement mammography unit will improve overall patient scheduling and productivity such that the overall operating costs will likely decrease once the equipment becomes operational.

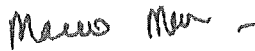
As noted above, the replacement equipment will cost less than two million dollars (\$2,000,000); it will be purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. The cost estimate included here takes into account the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment and reflects the greater of the fair market value or cost of the equipment as required by N.C. Gen. Stat. Ann. § 131E-176.

No other diagnostic equipment is proposed to be purchased or replaced at this time at the existing Diagnostic Center located at 1126 N. Church Street, Suite 200 in Greensboro, North Carolina.

In accordance with 10A NCAC 14C.0303, the Replacement Equipment Administrative Rule, Solis Mammography agrees that the acquisition of the equipment 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. No increases in patient charges are anticipated within this period.

Thank you for your consideration. Please call me at 469-398-4103 if you have any questions.

Sincerely,



Mano Mahadeva
Chief Financial Officer

Exhibit A:

Equipment Comparison		EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)		Mammography System	Mammography System
Manufacturer of Equipment		Hologic	Hologic
Model Number		Selenia Tungsten (2D)	Selenia Dimensions (3D)
Serial Number		2840513w7789W	81001143194
Provider's Method of Identifying Equipment		Selenia Tungsten (2D)	Selenia Dimensions (3D)
Specify if Mobile or Fixed		Fixed	Fixed
Date of Acquisition of Each Component		7/1/2013	
Does Provider Hold Title to Equipment or Have a Capital Lease?		Holds Title	
Specify if Equipment Was/Is New or Used When Acquired		New	
Total Capital Cost of Project (no construction involved)		NA	
Total Cost of Equipment		NA	See Below
Fair Market Value of Equipment		NA	\$250,000 (Ex. B)
Physics Survey / Shielding Design / Post Installation Survey			\$3,495
Equipment Components			\$25,500
Inter-state System Relocation and Associated Costs			\$11,681
ACR Fees			\$1,700
Total Capital Cost of Project (no construction involved)			\$292,376
Net Purchase Price of Equipment (Existing Equipment Purchased 7/1/2013)		\$188,147	
Locations Where Operated Currently		1126 N. Church Street, Suite 200 Greensboro NC	4600 New Linden Hill Rd. Wilmington, DE 19808
Number Days In Use/To be Used in N.C. Per Year (5.5 days / week x 52)		286	286
Percent of Change in Patient Charges (by Procedure)			0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)			Less than 5%
Type of Procedures Currently Performed on Existing Equipment		Mammography	
Type of Procedures New Equipment is Capable of Performing			Mammography

EXHIBIT B:

Equipment

Elia Health, Inc.
101 Lindenwood Drive, Suite 225
Malvern, PA

elia health

INVOICE FOR 3D UNIT #81001143194

11/16/2016

BILL TO

Solis North Carolina Diagnostic Imaging and
Breast Cancer Management, Inc., d/b/a Solis
Mammography
15601 Dallas Parkway, Suite 500
Addison, TX 75001
Attn: COO

SHIP TO

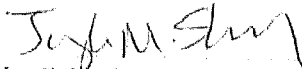
Solis Mammography
1126 N. Church St.
Suite 200
Greensboro, NC 27401

QUANTITY	DESCRIPTION	EQUIP. LOCATION	SERIAL NO.	TOTAL
1	Hologic Selenia Dimensions 3D Mammography System with CAD	4600 New Linden Hill Rd. Wilmington, DE 19808	81001143194	\$250,000

TOTAL DUE

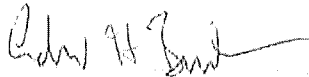
\$250,000.00

APPROVED BY:
ELLA HEALTH, INC.



Joe Shikorsky
President & CEO

**SOLIS NORTH CAROLINA DIAGNOSTIC IMAGING
AND BREAST CANCER MGMT, INC.,
D/B/A SOLIS MAMMOGRAPHY**



Edward H. Bucknam
Chief Operating Officer

LANDAUER[®] MEDICAL PHYSICS

1911 Evans Road
Cary, NC 27513
(888) 831-4880 (Office)
(888) 883-5909 (FAX)
Quotes@LandauerMP.

Customer Authorization

QUOTE #: LMP-001767-16
QUOTATION DATE: 11/15/2016

Quote Type/GPO:
GPO NUMBER:
GLN NUMBER:

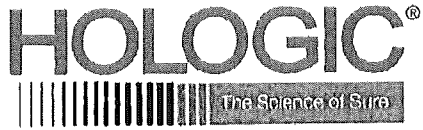
EXPIRATION DATE: 1/14/2017
PAYMENT TERMS: Net 30

Service Delivery Location:
Facility Name: Solis Mammography - Greensboro
POC: Val Hopkins
Address: 1126 N. Church St., Suite 200
City, State, Zip: Greensboro, NC 27401
Phone: (336) 379-0941
Fax:
E-Mail: vhopkins@solismammo.com

Bill To Address:
Facility Name: Solis Mammography - Greensboro
POC: Accounts Payable
Address: 1126 N. Church St., Suite 200
City, State, Zip: Greensboro, NC 27401
Phone:
Fax:
E-Mail: prodinusuz@solismammo.com

Manufacturer	Model	Serial Number	Clinical Engineering/ State ID Number	Service Code	Description of Service	Visits/ Instances	QTY	Facility Price Per Visit/Instance	Total Per Visit/Instance
				MAM-T	Digital Tomo Mammo ACR Physics Survey (includes 1 visit per yr. with one RWS, and one printer)	1	1	\$ 2,295.00	\$ 2,295.00
				SHIELD-MAM	Shielding Design - Mammography DX	1	1	\$ 600.00	\$ 600.00
				RPS-AREA	Post Installation Area Radiation Scatter Survey/Radiation Protection Survey (RPS)	1	1	\$ 600.00	\$ 600.00

Contract Total: \$3,495.00



Quotation

PLEASE REFER TO THIS NUMBER ON ALL CORRESPONDENCES AND ORDERS
Buying Group: SOLIS WOMEN'S HEALTH - MAMMO
SOLIS PRICING ATTACHMENT DTD 2-27-2015

Quote #: Q-02094

Status: Approved

Quote Expiration Date: 1/1/2017

TO:

CUSTOMER NAME	CUSTOMER NUMBER
SOLIS WOMENS HEALTH AT BERTRAND BREAST CENTER	88799
BILL TO ADDRESS	SHIP TO ADDRESS
1126 N CHURCH ST GREENSBORO NC US 27401	1126 N CHURCH ST GREENSBORO NC US 27401

We are pleased to offer you the products listed on the condition that this Quotation and Hologic's Master Sales Terms and Conditions comprise the complete and exclusive statement of the contract between us. This Quotation is based on the information known by Hologic regarding your needs as of the date the Quotation is generated. **This Quotation and the terms and conditions set forth in SOLIS WOMEN'S HEALTH - Mammo 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.** This offer is subject to change or withdrawal by Hologic prior to acceptance. 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.
 36 Apple Ridge Road
 Danbury, CT 06810
 ATTN: Sales Administration
 Fax: (203) 731-8463
 capitalorders@hologic.com

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.

ATTN: Valerie Hopkins

Phone: 3363790941

Fax:

Email:

vhopkins@solismammography.com

Quote Date	Hologic Representative	FOB	Payment Terms	Est. Del. Date	Quote Currency
11/2/2016	Lynn Smith lynn.smith@hologic.com	DESTINATION NO CHARGE	30 NET	2/20/2017	USD

Qty	Product Name	Description	List Price	Unit Price	Extended Price
1	R2UP-2002	CENOVA DIGITAL PORT LICENSE TRANSFER	\$10,000.00	\$1,000.00	\$1,000.00
1	R2SYS-2200	CENOVA 2D TOWER SYSTEM	\$15,000.00	\$3,000.00	\$3,000.00
1	ASY-04194	KIT, DIAGNOSTIC PADDLES	\$4,000.00	\$3,600.00	\$3,600.00
1	ASY-01993	PADDLE ASSEMBLY, LOCALIZATION, RECTANGULAR OPENING, 10CM	\$000.00	\$750.00	\$750.00
1	ASY-04165	KIT, BARCODE SCANNER	\$3,250.00	\$3,250.00	\$3,250.00
1	CMP-01404	MONITOR, 21.3" 3MP 2048X1538 BARCO NIO COLOR, TFT AM COLOR LCD IPS, LED BACKLIGHTS, DVID DUAL LINK, DISPLAYPORT	\$18,000.00	\$13,900.00	\$13,900.00

List Price Total: USD 51,250.00
Discount: USD 25,750.00
Final Quote Price: USD 25,500.00

12 Months Parts and Labor; Dimensions an additional 6 Months (18)

Quote #: Q-02094-1

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.

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.

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

SOLIS WOMEN'S HEALTH AT BERTRAND BREAST CENTER

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
R2UP-2002	Provides license transfer from one configuration to another. Allows an existing ImageChecker CAD port or Quantra port to be migrated from one digital manufacturer FFDM model to another manufacturer's FFDM model. Also allows an existing ImageChecker CAD port, DigitalNow HD or Quantra port to be migrated from one Cenova server to another, preserving the investment in R2 Image Analytics software products. Includes: * Support for transferring one ImageChecker CAD port or Quantra port: * Between manufacturers (e.g. GE to Hologic) * Between models (e.g. Hologic Selenia to Hologic Selenia Dimensions) * From one Cenova server to another NOTE: Cenova serial number must be provided.
R2SYS-2200	The Cenova Digital Mammography Processing System hosts Image Analytics software applications. Image Analytics licenses are sold separately. Includes: - Hologic's latest Cenova Processing Unit Server - Windows 7 operating system - Dynamic resource management and case control - Output transmission re-try mechanism - Flexible output routing to multiple output destinations - Computer Server (6U) - Compact footprint - License dongle - Hologic Connect remote system diagnostics software for post-installation service and applications support; conforms with Verisign security - Note: This server can be used horizontally, and rack mounted by ordering R2ACC-2001. (R2SYS-2200-1U is a thinner server, ships with a rack mount and is preferred for rack mounting.) Requires: - The system is designed to process 2D images only. - Specify manufacturer, and model of FFDM system at time of order - Verify with the Technical team that the number of licenses on a server can be adequately supported.
ASY-04194	The optional expanded compression paddle kit is designed to enhance both screening and diagnostic patient imaging procedures. Includes: • Small breast screening paddle • frameless spot paddle • 7.5cm spot contact paddle • 7.5cm spot magnification paddle
ASY-01993	Selenia Dimensions 10 cm wide localization paddle with 5x7 cm rectangular opening. Features a Grid Locator that is both visible clinically and in X-ray images.
ASY-04165	The barcode scanner option offers an enhancement to the workflow of the AWS 5000. It promotes ease and accuracy in the selection of patients from a worklist and can expedite the imaging procedure.
CMP-01404	A 3 Megapixel, medical-grade, DICOM gray scale monitor. Ideally suited for technologist quality control, including inspection of images for motion blur, and targeting of microcalcifications during biopsy procedures.

HOLOGIC®

November 18, 2016
Ella Health Inc
540 Woodbourne Rd
Langhorne, PA 19047

Attention: Brady Briscoe

MODEL: Selenia Dimensions
SERIAL NUMBER: 81003143210

- Inter-state system relocation in the continental US.
Includes FE labor & travel, packaging, material & freight, AEC recalibration
If parts are required to bring the system within Hologic specifications or
longer cables are required for the new room, the cost is additional and will be
invoiced separately.
Training is not included with the move quote and will need to be quoted by
the training department.

\$ 11,681.00

All moves require a two-week lead time.

**Expedited moves (within the 2 weeks)are available for a surcharge of \$
500.00**

Quote is valid for 90 days.

The system will perform according to Hologic's manufacturing specifications
upon completion of relocation.

To complete the process, please choose one of the following methods of payment:

Wire transfer _____ **Check** _____ **PO#** _____

If paying by credit card, please complete the following:

Credit Card number _____ Expiration date _____

Name as it appears on the card _____

Authorized signature _____

**The move will be scheduled two to three weeks after payment is received and
processed by Hologic. All methods of payment must be received and
processed prior to scheduling the move.**

Accreditation Cycle	Old Fee	2016 Fee
→Initial, Renewal, Reinstatement – 1st unit	\$1475	\$1700
Initial, Renewal, Reinstatement – each additional unit	\$1300	\$1500
Repeat – each unit	\$700	\$825
New Unit (mid cycle)	\$850	\$1000

Source: ACR website