



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

October 27, 2020

Bill Schiff
Bill.schiff@dm.duke.edu

No Review

Record #: 3395
Project ID: J-8613-10
Facility Name: Private Diagnostic Clinic, PLLC
FID #: 101140
Business Name: Private Diagnostic Clinic, PLLC
Business #: 1478
Project Description: Acquire new medical diagnostic equipment for established diagnostic center
County: Durham

Dear Mr. Schiff:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence 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 Section 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,

Kim Meymandi
Project Analyst

Martha J. Frisone
Chief

cc: Radiation Protection Section, DHHSR

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

October 15, 2020

Ms. Martha Frisone
Chief, Healthcare Planning & Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27626-0530

RE: Request for No Review Determination Regarding Duke Medicine Specialty Care Page Road Purchase of Medical Diagnostic Equipment / Durham County / Project I.D. #J-8613-10 / FID #101140

Dear Ms. Frisone:

The purpose of this letter is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") that Private Diagnostic Clinic, PLLC (PDC) plans to purchase medical diagnostic equipment, which will be located in its Duke Medicine Specialty Care Page Road Diagnostic Center (FID #101140).¹

PDC requests the Agency to confirm that purchase of the following medical diagnostic equipment for the Duke Medicine Specialty Care Page Road diagnostic center is non-reviewable because it does not constitute a new institutional health service. Under North Carolina law, the purchase of medical diagnostic equipment for an existing diagnostic center is not subject to CON review unless it qualifies as "major medical equipment" under the statute. To qualify as "major medical equipment," the cost of acquiring each piece of medical diagnostic equipment would need to exceed \$750,000. PDC does not intend to purchase any equipment which exceeds this threshold.

The table on the following page summarizes the cost to acquire each piece of medical diagnostic equipment, including the cost of renovation and all associated professional fees.

¹ For information purposes, PDC is submitting a concurrent request for No Review determination regarding the relocation of Duke Medicine Specialty Care Page Road diagnostic center from 4709 Creekstone Drive, Durham, NC 27703 to 5601 Arringdon Park Drive, Morrisville, NC. The medical diagnostic equipment described in this request will be developed at the Arringdon Park Drive location.

Equipment Description	Cost Per Unit	Upfit Cost	Total Cost To Acquire Medical Diagnostic Equipment
EOS (Orthopedic Imaging)	\$540,000	\$97,436	\$637,436
X-ray Machine	\$197,274	\$97,436	\$294,710
X-ray Machine	\$197,274	\$97,436	\$294,710
Corneal Topography	\$21,991	\$1,215	\$23,206
Corneal Topography	\$21,991	\$1,215	\$23,206
IOL Master	\$72,457	\$540	\$72,997
Lenstar	\$42,390	\$540	\$42,930
Rolling Slit Lamp	\$21,246	\$540	\$21,786
Rolling Slit Lamp	\$21,246	\$540	\$21,786
Rolling Slit Lamp	\$21,246	\$540	\$21,786
Clarus	\$110,605	\$1,215	\$111,820
Autorefractor	\$13,495	\$135	\$13,630
Autorefractor	\$13,495	\$135	\$13,630
Autorefractor	\$13,495	\$135	\$13,630
Slit Lamp	\$18,279	\$540	\$18,819
Slit Lamp	\$18,279	\$540	\$18,819
Slit Lamp	\$18,279	\$540	\$18,819
Slit Lamp	\$18,279	\$540	\$18,819
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Slit Lamp	\$18,279	\$540	\$18,819
Slit Lamp	\$18,279	\$540	\$18,819
Slit Lamp	\$18,279	\$540	\$18,819

For information purposes, Attachment A includes cost documentation for the EOS machine and Attachment B includes cost documentation for the X-ray machines.

Based on the project described above, PDC requests the Agency to confirm that PDC's purchase of the identified medical diagnostic equipment for Duke Medicine Specialty Care Page Road diagnostic center is not subject to CON review.

Thank you for your attention to this matter. Please contact me at 919.668.1823 or bill.schiff@duke.edu regarding any questions concerning this request.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bill Schiff', with a stylized flourish at the end.

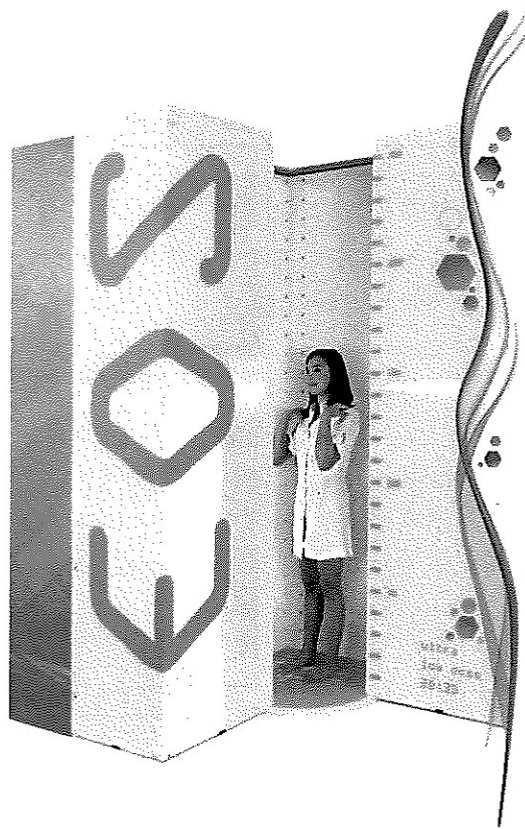
Bill Schiff
Vice President, Strategic Services & Network Development
Private Diagnostic Clinic, PLLC

Attachments:
EOS Cost Documentation
X-ray Cost Documentation

Attachment A: EOS Machine



SALES AGREEMENT



Customer: Duke University Health System
Site Installation Address: 2301 Erwin Rd. Durham, NY 27710
Quotation Number: 380E
Sales Agreement Issue Date: March 26, 2019
EOS Regional Sales Manager: Matt Fendrich (561)268-6870

EOS imaging SA
10 rue Mercœur
75011 Paris France
+33 (0) 155 25 60 60

EOS imaging, Inc.
185 Alewife Brook Pkwy # 205
Cambridge, MA 02138 USA
+1 (678) 564 5400

www.eos-imaging.com

EOS Imaging is pleased to submit this agreement to the Purchaser for the products and services described herein and at the prices and terms and conditions set forth below, including:

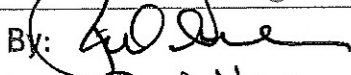
- the Quotation in Part A,
- the Special Terms and Conditions in Part B,
- [Click here](#) to review the Product Description Part C,
- [Click here](#) to review the Installation Requirements Part D,
- General Terms & Conditions for Purchase & Service in Part E together with any other special terms or agreements that may be attached to this agreement as additional schedules and/or exhibits (collectively, the "Agreement").

As further described in this Agreement, product installation costs are included in the total amount due under this Agreement (the "Purchase Price") unless otherwise indicated. Other charges, like transport, insurance and taxes, if any, are in addition to the purchase price and are payable by Purchaser upon receipt of each invoice for such charges and/or taxes.

Sales Agreement Summary

PRODUCT CONFIGURATION	EOS acquisition system with 1 sterEOS workstation and selected options. See Part A
TOTAL PRICE IN US Dollars (\$)	\$540,000.00- See Part A
PAYMENT TERMS	See Part B
VALID UNTIL	3/29/2019
DELIVERY TERMS	FCA
AVAILABILITY	Approximately 3 months - See Part B
WARRANTY	1 year labor and parts
REQUESTED DELIVERY DATE	TBD

Customer Agreement

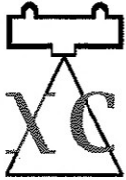
By: 
 Name: Paul Newman
 Title: Senior VP
 Date: 3/27/19

EOS imaging

Approved by:
 Name: Graham Heaven
 Title: VP of Sales, NAM
 Date:



Attachment B: X-ray Machine



TRIANGLE X-RAY COMPANY

4900 Thornton Rd., Suite 117
Raleigh, NC 27616

Phone #	Fax #
919-876-6156	919-872-3986

Invoice

DATE	INVOICE NO
6/29/2020	20201551-C

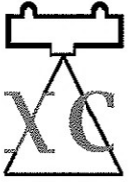
BILL TO
First Citizens Bank & Trust Co. 1230 Main Street Columbia, SC 29201 Attn: Angela Baggott

Ship To
Duke Orthopaedics of Arrington 5601 Arrington Park Drive Durham, NC 27560

TICKET NO	WORK DATE	REP	TERMS	DELIVERY	JOB DESCRIPTION
	6/29/2020	KB	See Below	Best Way	PO #60238

ITEM CODE	DESCRIPTION	QTY	PRICE EACH	AMOUNT
Digital-Equip...	(6) Carestream/Quantum Overhead Radiographic Systems with DRX-1 CORE Systems to include: -(6) 65kW/150kVp Digital Deluxe Radiographic Generator -(6) DRX Core 3543 Wireless Detector for Ascend -(18) DRX Detector Battery -(6) Detector Battery Charger -(6) Auxilliary Power Supply -(6) AEC Electronics for CSH Generator -(12) R80-AEC Ionization Chamber -(6) Ceiling Mounted Tubestand with Autotracking -(12) Longitudinal Rails 14Ft -(6) Techvision -(6) Quiet Lift Levating Float Top table -(6) Grid 103LPI 10:1 Ratio 34-44 Focal -(12) Wireless On Demand Tray for DRX Wall Stand and Table -(6) Interface Cable -(6) DRX Digital Wall Stand -(6) Grid 103LPI 10:1 Ratio 40-72 Focal -(6) Overhead Patient Handgrips -(6) Side Mounted Patient Handgrips -(6) Manula Collimator -(6) Dose Monitoring DAP Meter -(6) Dose Reporting Software -(6) Admin Analysis and Reporting Software -(6) Remote Management Services -(6) Quantum Branding Kit for QRAD -(6) DRX Digital Console **Drop Rider included for Years 1 and 2** (1) Previously Owned Carestream QRAD Syste to include:	1	197,273.75	197,273.75

Thank you for your business	Total
	Sales Tax (7.5%)
	Payments/Credits
** Effective Immediately ** A late payment charge (18% annually) will be imposed on items that are not paid within 30 days of the invoice date. Make checks payable to: Triangle X-Ray and include the invoice number for proper credit. Credit card payments for invoices exceeding \$5,000 will be charged an additional 3.0% surcharge. [EIN# 27-0041403]	Balance Due



TRIANGLE X-RAY COMPANY

4900 Thornton Rd., Suite 117
Raleigh, NC 27616

Phone #	Fax #
919-876-6156	919-872-3986

Invoice

DATE	INVOICE NO
6/29/2020	20201551-C

BILL TO
First Citizens Bank & Trust Co. 1230 Main Street Columbia, SC 29201 Attn: Angela Baggott

Ship To
Duke Orthopaedics of Arrington 5601 Arrington Park Drive Durham, NC 27560

TICKET NO	WORK DATE	REP	TERMS	DELIVERY	JOB DESCRIPTION
	6/29/2020	KB	See Below	Best Way	PO #60238

ITEM CODE	DESCRIPTION	QTY	PRICE EACH	AMOUNT
	-50kW/125kVp Digital Deluxe Generator -X-Ray Tube 3" -High Speed Rotor (2) FDR D-EVO GL Long Length DR Detector to include: -(2) FDR D-EVO GL -(2) FDR D-EVO GL Detector -(2) Mobile Detector Stand -(2) FDX Console -(2) Stitching Software and DICOM Modality Worklist -(2) SE Cable 10M -(2) FDX Console Dynamic Visualization 2 Software -(2) FDX Console Virtual Grid -(2) FDR D-EVO GL Physical Grid 10:1 Ratio 103LPI			
	This invoice replaces original invoice 20193042 (Installation Delayed)			

Thank you for your business	Total	\$197,273.75
	Sales Tax (7.5%)	\$0.00
	Payments/Credits	\$0.00
	Balance Due	\$197,273.75

**** Effective Immediately ****

A late payment charge (18% annually) will be imposed on items that are not paid within 30 days of the invoice date. Make checks payable to: Triangle X-Ray and include the invoice number for proper credit. Credit card payments for invoices exceeding \$5,000 will be charged an additional 3.0% surcharge.
[EIN# 27-0041403]

From: [Michaela McMorris](#)
To: [Waller, Martha K](#)
Cc: [Frisone, Martha](#); [Sara Holleran](#); [Karin Sandlin](#)
Subject: [External] No Review Determination - Duke Medicine Specialty Care Page Road (FID# 101140)
Date: Thursday, October 22, 2020 2:31:38 PM
Attachments: [PDC Request for No Review Determination - Relocate Existing Diagnostic Center Oct 2020.pdf](#)
[PDC Request for No Review Determination - New Diagnostic Equipment Oct 2020.pdf](#)

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

Hello,

Attached are two requests for no review determination related to Duke Medicine Specialty Care Page Road (FID# 101140).

Please contact me if you have any questions.

Best,

Michaela McMorris, MHA

Planning Analyst
Private Diagnostic Clinic, PLLC
Duke Health
919-668-6607
michaela.mcmorris@duke.edu