

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 31, 2024

Emily Cromer

emily.cromer@unchealth.unc.edu

No Review

Record #: 4605

Date of Request: September 27, 2024

Facility Name: University of North Carolina Medical Center

FID #: 923517

Business Name: UNC Health Care System

Business #: 2991

Project Description: Acquire a portable CT scanner

County: Orange

Dear Ms. Cromer:

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 representation in your request and 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. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Cynthia Bradford, Project Analyst

Micheala Mitchell, Chief

cc: Acute and Home Care Licensure and Certification 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

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



September 27, 2024

VIA ELECTRONIC MAIL

Micheala Mitchell, Chief Cynthia Bradford, Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation

Re: No Review Determination Request by UNC Hospitals to Acquire CT Scanner

Dear Ms. Mitchell and Ms. Bradford:

UNC Hospitals ("UNCH") seeks to acquire a BodyTom 64 Core System Portable CT Scanner from NeuroLogica Corporation and locate it on its main campus in Chapel Hill. The purpose of this letter is to provide the Agency with notice and to request a determination that the purchase of the CT Scanner does not require Certificate of Need ("CON") review because it does not exceed the threshold dollar amount for major medical equipment contained in N.C. Gen. Stat. § 131E-176(14o).

The statutory definition of "major medical equipment" under N.C. Gen. Stat. § 131E-176(14o) is:

Major medical equipment. - 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 two million dollars (\$2,000,000). In determining whether the major medical equipment costs more than two million dollars (\$2,000,000), 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.

As noted in the NeuroLogica Corporation quote, attached as Exhibit A, the total capital cost of purchasing and installing the CT Scanner is \$569,000. UNCH will incur no other capital costs associated with acquiring, installing, or operationalizing the CT scanner.

Based upon the above facts, the CT Scanner does not meet the definition of major medical equipment. UNCH hereby requests that the Agency provide a written response confirming that the purchase of the CT Scanner to be used on its main campus in Chapel Hill does not require CON approval. Please do not hesitate to contact me at Emily.Cromer@unchealth.unc.edu if you require any additional information.

Sincerely,

Emily Cromer

Emily Cromer

Director of Regulatory Affairs & Facility Strategy

UNC Health



Quote # Q-14386-1 Quote Date: 8/13/2024 Valid Until: 10/31/2024



*Picture include optional accessories

Account Executive Camp Jenkins

Email cjenkins@neurologica.com

Phone (336) 681-0399

F.O.B. Point Danvers, MA Payment Terms Net 30

Customer Information

UNC Medical Center (FKA University of North Carolina Hospitals - Memorial Hospital) 101 Manning Dr Chapel Hill, North Carolina 27514 United States

Name

Phone

Email

Project Manager

Eve Pedersen

eve.pedersen@unchealth.unc.edu



Comments: Discount Contingent Upon Receipt of Purchase Order Prior to Quote Expiration Date

UNC Medical Center (FKA University of North Carolina Hospitals -Memorial Hospital) 101 Manning Dr Chapel Hill, North Carolina 27514

SHIPPING:

RIGGING:

TOTAL:

\$5,250.00

\$5,700.00

\$569,000.00

QTY	PART#	DESCRIPTION	UNIT PRICE	Discount	AMOUNT
1	0-NL4100-001	BodyTom® 64 Core System Mobile 64 MultiSlice CT Scanner Axial and Helical Scanning 2D/3D Software Multi Planar Reconstruction (MPR) 3D Volumetric Reconstruction Metal Artifact Reduction (MAR)	\$924,000.00	\$425,950.00	\$498,050.00
1	0-00003-001	CT Perfusion	\$16,000.00	\$16,000.00	\$0.00
1	0-00059-001	CT Angiography with Bolus Tracking	\$16,000.00	\$16,000.00	\$0.00
1	0-00056-001	Noise Reduction	\$16,000.00	\$16,000.00	\$0.00
1	0-00132-001	BodyTom MODO Workstation Cart (120v)	\$39,175.00	\$39,175.00	\$0.00
1	NS-500-1002	Stille Medstone5 CV	\$35,000.00	\$0.00	\$35,000.00
1	0-00097-001	8 Days New System Onsite Training & Case Support Maximum of 6 Technologists Two complimentary follow up days to be used within the first 12 months	\$25,000.00	\$0.00	\$25,000.00
				SUBTOTAL:	\$1,071,175.00
				DISCOUNT:	\$513,125.00

Warranty Service Agreement 12 months



UNC Medical Center (FKA University of North Carolina Hospitals -Memorial Hospital) 101 Manning Dr Chapel Hill, North Carolina 27514

QTY	PART#	DESCRIPTION	UNIT PRICE	AMOUNT
0	0-00129-001	Service Contract Coverage includes: Labor and travel coverage at no charge from 8:00 a.m. to 5:00 p.m., Monday—Friday, excluding holidays Telephone Support (within 1 hour) 24 hours per day, 7 days per week Onsite personnel (within 24 hours) Onsite Spare part (within 24 hours) Toom Warranty on all parts including X-ray Tube Preferred rates for labor and travel outside coverage hours. (\$325/hr). Normal rate is \$450/hr The completion of all the required routine maintenance. Uptime guarantee of 95% Any required software updates (Safety or specification) Routine maintenance is required to satisfy the conditions of warranty.	\$85,000.00	\$0.00
			SUBTOTAL:	\$0.00
			TOTAL:	\$0.00



TERMS AND CONDITIONS OF SALE

All purchases of equipment ("Equipment") from NeuroLogica Corporation (the "Seller") by the purchaser ("Purchaser") shall be governed by these terms and conditions of sale (these "Terms"). These Terms and any exhibits shall control over any conflicting, inconsistent or additional terms or conditions or any purchase order of Purchaser (including any terms and conditions of Purchaser) and all such conflicting, inconsistent or additional terms are rejected by Seller and shall have no effect.

ORDERS. All orders to purchase Equipment shall be made in writing and shall be subject to the written acceptance of the Seller. Seller shall not be obligated to accept any requested delivery/receipt date that is less than thirty (30) calendar days from the date of the relevant Purchase Order. QUOTATIONS AND PRICES. Seller's prices and quotations are subject to the following:

- (a) Quotations are only solicitations for offers and not offers which may be accepted by the Purchaser. All prices quoted herein are valid for the period of time provided under "Valid Until" date contained in the quotation. If a purchase order is not delivered to, and accepted by, NeuroLogica by the "Valid Until" date, then the quotation shall be deemed withdrawn as of such date, unless earlier withdrawn by notice to Purchaser by Seller.

 (b) Published prices are subject to change without notice.
- (c) All prices quoted shall be exclusive of the costs of transportation or insurance, taxes, including without limitation, any sales, use or similar tax, license fees, customs fees, duties and other charges related thereto, which shall be the responsibility of Purchaser. Any such costs shall be separately itemized on Seller's invoices and paid by Purchaser, or, in lieu thereof, Purchaser shall furnish Seller a properly executed tax exemption certificate prior to shipment.
- (d) All prices and quotations and any discussion regarding the same are confidential and proprietary information of the Seller and may not be disclosed to any third party.

TERMS OF PAYMENT. Payment shall be made in U.S. Dollars. 20% Deposit is required with purchase order and balance payment is due thirty (30) days from the date of invoice. Late payment penalties will apply to late payments. All sales are subject to prior credit approval by Seller. If the above terms of payment are not met, Seller may, in its sole discretion, in addition to other remedies, withhold all warranty service, training and technical service and support. Invoices not paid when due shall be subject to a late charge equal to 1% of the amount of the invoice or the highest lawful rate which may be charged to Buyer, whichever is less. Buyer shall also pay reasonable attorney's fees, collection agency fees and expenses should the invoices associated with this Order be referred to an attorney or collection agency for collection.

TRANSPORTATION AND RISK OF LOSS. All shipments shall be F.O.B. Danvers Massachusetts and title and risk of loss of damage shall pass to Purchaser upon delivery to carrier by Seller. Seller does not accept any liability for losses or added costs due to delivery delays.

RETURNS. Any returns of Equipment must be authorized by Seller in writing and will be subject to a 20% (of purchase price) restocking charge. CANCELLATIONS: Any cancellation of Equipment ordered but not delivered to a common carrier must be received in writing and will be subject to a 5% (of purchase price) charge.

SECURITY INTEREST. Seller shall retain a security interest in the Equipment until the entire balance of the Equipment price and all other monies payable hereunder are paid in full. Purchaser shall execute, upon request by Seller, financing statements deemed necessary or desirable by Seller to perfect its security interest in the Equipment. Purchaser authorizes Seller to file a copy of this security agreement or a financing statement with the appropriate state authorities at any time thereafter as a financing statement in order to perfect Seller's security interest. A financing statement may be filed without Purchaser's signature on the basis of this security agreement were allowed by law. Purchaser shall keep the Equipment in good order and repair until the purchase price has been paid in full and shall promptly pay all taxes and assessments upon purchase of the Equipment or use of the Equipment.

INSURANCE. Purchaser shall maintain adequate and appropriate insurance policies in relation to its obligations under these Terms, which shall include property damage insurance to the Equipment for the full replacement value thereof. Until full payment for the Equipment has been made, Seller shall be added as an additional loss payee on such insurance policies. As evidence of such coverage, prior to shipment of the Equipment, Purchaser shall provide to Seller a certificate of insurance.

INSTALLATION AND ACCEPTANCE. Purchaser shall provide a suitable installation environment and the Site shall be ready to receive the Equipment at the time scheduled for the delivery date. Purchaser shall provide adequate working space within reasonable distance of the Equipment for use by Seller's personnel. Seller or its representatives shall install the Equipment during Purchaser's normal working hours. Equipment shall be deemed accepted by Purchaser unless written notice of nonconformity is received within fourteen (14) days of installation. Use of Equipment by Purchaser or any of its agents, employees, or licensees, for any purpose (other than to determine that it meets specifications) after delivery thereof shall constitute acceptance.

WARRANTY. SELLER WARRANTS TO PURCHASER THAT THE EQUIPMENT SHALL BE IN GOOD WORKING ORDER ON THE DATE OF DELIVERY AND THAT THE EQUIPMENT SHALL BE FREE FROM DEFECTS IN MATERIAL AND WORKMANSHIP AT THE TIME OF DELIVERY AND FOR A PERIOD OF TWELVE MONTHS (12) THEREAFTER. SELLER'S OBLIGATIONS UNDER THE FOREGOING WARRANTY SHALL BE LIMITED SOLELY TO SELLER MAKING, AT ITS COST AND EXPENSE, SUCH REPAIRS AND REPLACEMENTS AS ARE NECESSARY TO PLACE THE EQUIPMENT IN GOOD WORKING ORDER AND TO CONFORM THE EQUIPMENT TO SELLER'S PUBLISHED SPECIFICATIONS. NOTWITHSTANDING THE FOREGOING, THE WARRANTY PROVIDED HEREIN SHALL BE VOID IN THE EVENT (1) THE EQUIPMENT FAILS, MALFUNCTIONS OR IS DAMAGED AS A RESULT OF IMPROPER HANDLING, MAINTENANCE, REMOVAL, MODIFICATION OR REPAIR BY PURCHASER OR A THIRD PARTY (NOT AUTHORIZED BY SELLER); OR (2) THE EQUIPMENT IS ACCIDENTALLY DAMAGED, SUBJECT TO ABUSE OR IMPROPER USE; OR (3) THE EQUIPMENT IS ALTERED OR DAMAGED SUCH THAT SELLER IS UNABLE TO VERIFY THE DEFECT WITH ITS NORMAL TEST EQUIPMENT. AS A FURTHER CONDITION OF THIS WARRANTY, PURCHASER IS REQUIRED TO REQUEST AND ALLOW THE SELLER'S SERVICE REPRESENTATIVE TO COMPLETE ALL ROUTINE MAINTENANCE ACCORDING TO THE ROUTINE MAINTENANCE SERVICE SCHEDULE. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.



LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN ANY WAY CONNECTED WITH THESE TERMS OR THE SALE AND PURCHASE OF THE EQUIPMENT, THE EQUIPMENT ITSELF OR ANY OTHER MATTER RELATED HERETO, INCLUDING WITHOUT LIMITATION, LOST BUSINESS OR LOST PROFITS, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. SELLER'S AGGREGATE LIABILITY TO PURCHASER ARISING OUT OF THESE TERMS OR THE SALE AND PURCHASE OF THE EQUIPMENT SHALL NOT EXCEED THE SUM PAID TO SELLER BY PURCHASER FOR THE EQUIPMENT SOLD HEREUNDER. IT IS FURTHER AGREED THAT SELLER SHALL HAVE NO LIABILITY TO PURCHASER, PURCHASER'S PATIENTS, OR ANY THIRD PARTIES FOR ANY DIRECT, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES CONCERNING THE EQUIPMENT, UNLESS SUCH DAMAGES ARE A DIRECT RESULT OF SELLER'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; PROVIDED, HOWEVER, THAT NOTHING IN THIS AGREEMENT SHALL DEPRIVE PURCHASER OF ANY RIGHTS IT MAY HAVE AGAINST ANY PERSON OTHER THAN SELLER.

INTELLECTUAL PROPERTY. No rights to any intellectual property residing in the Equipment, software, documentation, or any data furnished hereunder are granted except the right to use such intellectual property. Purchaser recognizes that, among other items, computer software necessary to the operation of the Equipment is confidential information belonging to Seller. Purchaser shall have no right to copy, reproduce or disclose to others in whole or in part any of the above without the prior written permission of Seller.

INDEMNITY. As an express condition of sale, Purchaser agrees to hold Seller and its parent, owners, subsidiaries and affiliates and their directors, officers, shareholders, employees and agents harmless from and against any claims, suits, losses, liabilities, injuries or damages (including, without limitation, reasonable attorneys' fees and litigation expenses) arising out of or in connection with: (i) use of the Equipment not in accordance with the Documentation; and (ii) all actions or omissions by Purchaser personnel (including employees and independent contractors) who use the Equipment. Seller agrees to hold Purchaser, its parent, owners, subsidiaries and affiliates and their directors, officers, shareholders, employees and agents harmless from and against any claims, suits, losses, liabilities, injuries or damages (including, without limitation, reasonable attorneys' fees and litigation expenses) arising out of or in connection with (i) any third party claims that the Equipment caused injury solely as a result of Seller's gross negligence or due to defects in material or workmanship of the Equipment for which Seller is legally liable.

GOVERNING LAW. These Terms shall be governed by the laws of the Commonwealth of Massachusetts, without giving effect to its provisions on conflicts of laws. Seller and Purchaser hereby submit to the jurisdiction of the state and federal courts located in the Commonwealth of Massachusetts and agree not to contest the jurisdiction of such courts. No action, regardless of form, arising out of, or in any way connected with, the Equipment or any service furnished, or to be furnished, may be brought by Purchaser more than (1) one year after the cause of action has accrued to Purchaser. FORCE MAJURE. Neither party shall be liable for any delay in performance, not to exceed six months, caused by any occurrence beyond its reasonable control, including but not limited to acts of God, power outages, wars, commencement or escalation of hostilities, terrorist acts, industrial disputes and governmental restrictions, strikes, labor disputes, floods, fires, accidents, and any such delay, not to exceed six months, shall not be considered a breach of this Agreement and such performance shall be excused for the number of days such occurrence reasonably prevents performance. SEVERABILITY. Each provision of these Terms shall be severable. If, for any reason, any provision herein is finally determined to be invalid and contrary to, or in conflict with, any existing or future law or regulation by a court or agency having valid jurisdiction, such determination shall not impair the operation or affect the remaining provisions of these Terms, and such remaining provisions will continue to be given full force and effect and bind the parties hereto. Each invalid provision shall be revised only to the extent necessary to bring it within the requirements of such law or regulation. ENTIRE AGREEMENT; NO WAIVER. These Terms, along with any purchase order and any and all exhibits hereto represents the entire understanding of the parties hereto and supersedes any prior understandings or agreements (whether oral or in writing) relating to the subject matter hereof. None of the terms of this Agreement can be waived, amended or modified except by an express agreement in writing signed by the parties. There are no representations, promises, warranties, covenants or undertakings other than those contained in this Agreement. No custom or practice of the parties hereto at variance with the terms hereof shall constitute a waiver of either party's right to demand exact compliance with any of the terms herein at any time. The failure of either party hereto to enforce, or the delay by either party hereto in enforcing, any or all of its rights under these Terms shall not be deemed as constituting a waiver or a modification thereof, and either party hereto may, within the time provided by applicable law, commence appropriate proceedings to enforce any or all of such rights.

 From:
 Mitchell, Micheala L

 To:
 Waller, Martha K

 Cc:
 Stancil, Tiffany C

Subject: FW: [External] UNC Hospitals No Review Request to Acquire CT Scanner

Date: Monday, September 30, 2024 4:33:38 PM

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

2024.09 No Review CT Scanner Med Center.pdf

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center Raleigh, NC 27699-2704 Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Mitchell, Micheala L

Sent: Friday, September 27, 2024 3:23 PM

To: Stancil, Tiffany C < Tiffany.Stancil@dhhs.nc.gov> **Cc:** Bradford, Cynthia L < cynthia.bradford@dhhs.nc.gov>

Subject: FW: [External] UNC Hospitals No Review Request to Acquire CT Scanner

Hi Tiffany,

Would you mind assigning this no review to Cindy?

Thank you,

Micheala Mitchell, JD

NC Department of Health and Human Services

Division of Health Service Regulation

Section Chief, Healthcare Planning and CON Section

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center Raleigh, NC 27699-2704 Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov

From: Cromer, Emily < Emily.Cromer@unchealth.unc.edu>

Sent: Friday, September 27, 2024 3:20 PM

To: Mitchell, Micheala L < Mitchell@dhhs.nc.gov; Bradford, Cynthia L

<cynthia.bradford@dhhs.nc.gov>

Subject: [External] UNC Hospitals No Review Request to Acquire CT Scanner

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Hi Micheala and Cindy,

Attached is a no review request for the acquisition of a CT scanner at UNC Hospitals' main campus in Chapel Hill. Please confirm receipt and let me know if you have any questions.

Thanks, Emily

Emily Cromer | Director of Regulatory Affairs & Facility Strategy UNC Health p (984) 215-6213 | m (919) 884-6213 emily.cromer@unchealth.unc.edu



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