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

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

July 3, 2014

Lynn DeJaco  
155 Memorial Drive  
P.O. Box 3000  
Pinehurst, NC 28374

Exempt from Review - Replacement Equipment  
Facility: FirstHealth Moore Regional Hospital  
Project Description: Replace cardiac catheterization unit located at FirstHealth Moore Regional Hospital  
County: Moore  
FID #: 943358

Dear Ms. DeJaco:

In response to your letter of June 4, 2014, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Toshiba Infinix-I Dual Plane cardiac catheterization unit, serial number 212480, to replace the existing Toshiba Infinix CS cardiac catheterization unit, serial number 212480. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Furthermore, please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section with the serial number of the new equipment to update the inventory.

Moreover, you need to contact the Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Tanya S. Rupp  
Project Analyst

Martha J. Frisone, Interim Chief  
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR  
Construction Section, DHSR  
Medical Facilities Planning Branch, DHSR

Certificate of Need Section  
www.ncdhhs.gov  
Telephone: 919-855-3873 • Fax: 919-733-8139  
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
June 4, 2014

Ms. Martha Frisone
Chief, Certificate of Need Section
Department of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination for Replacement of Cardiac Catheterization Unit located at FirstHealth Moore Regional Hospital / Moore County

Dear Mr. Smith:

Pursuant to T10 NCAC 3R.0304(a), FirstHealth Moore Regional Hospital (FMRH) intends to replace an existing cardiac catheterization unit and requests a determination that such replacement falls within the definition of NCGS 131E-184 (a)(7) and the regulations set out in T10.3R.0214, as exempt from review.

Statement of Facts

FMRH proposes to replace an existing Toshiba Infinix CS cardiac catheterization unit that was purchased in January 2004. The existing cardiac catheterization unit is outdated and has limited capabilities in its ability to be upgraded. FMRH has determined that it would be most effective to replace the existing cardiac catheterization unit with state-of-the-art technology that can be further upgraded in the future.

Exemption from Review

Pursuant to NCGS 131E-184(a)(7) "The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."

NCGS 131E-176(22a) defines "replacement equipment" as equipment that cost less than $2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.
Applicable Regulations

NCAC T10: 03R .0214 defines “comparable medical equipment” as equipment that is functionally similar and which is used for the same diagnostic or treatment purposes. Replacement equipment is comparable if:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and

(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and

(3) the acquisition of the equipment does 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.

Replacement equipment is not comparable to the equipment being replaced if the replacement equipment is 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.

Compliance

FirstHealth Moore Regional Hospital hereby certifies that:

1. The estimated replacement cost for the cardiac catheterization unit is $1,174,250. This assumes purchase of a Toshiba Infinix-I Dual Plane cardiovascular system per the attached quotations (Exhibit A). Renovation and A/E costs are $98,000 for a total project cost of $1,272,250 (Exhibit B).

2. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be dismantled by Toshiba Medical Systems. A comparison of the existing and replacement equipment is provided in Exhibit C.

3. The replacement equipment is functionally similar to existing equipment and will be used for the same diagnostic and/or treatment procedures as the equipment currently in use.

4. No increase in charges will occur within the first twelve months after the replacement equipment is acquired.

5. The average cost per cardiac catheterization procedure increases by $0 (0%) as a result of the replacement.
Determination Requested

FirstHealth Moore Regional Hospital requests that the Division of Health Service Regulation make a determination that replacement of existing cardiac catheterization unit as proposed herein does not constitute a new institutional health service and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-715-1981.

Sincerely,

[Signature]

Lynn DeJaco
Chief Financial Officer

Attachments:  
Exhibit A - Vendor Quotes  
Exhibit B - Proposed Total Capital Cost of Project  
Exhibit C - Existing/Replacement Equipment Comparison
TOYOTA AMERICA MEDICAL SYSTEMS, INC.

QUOTATION/ORDER
ORDER SUMMARY

DATE: 3/6/2014

PRESENTED TO: (COMPLETE LEGAL NAME)
FIRSTHEALTH MOORE REGIONAL HOSPITAL
35 MEMORIAL DR
PINEHURST, NC. 28374

DELIVER TO:
FIRSTHEALTH MOORE REGIONAL HOSPITAL
35 MEMORIAL DR
PINEHURST, NC. 28374

SID NO: 30012973
QUOTE NO: 46248

EQUIPMENT SUMMARY:
DPIB/1216.000

INFINIX-I DUAL PLANE CARDIOVASCULAR SYSTEM

VASCULAR DP-I/FD2 SYSTEM WITH CAT-850B TABLE

DP-I/FD2 MAIN SYSTEM WITH CAT-850B TABLE

STEPPING UNIT FOR CAT-850B

SITE LAYOUT TO BE DETERMINED

21 INCH COLOR MONITOR

VGA CONNECTION ADAPTER

LCD FLAT-PANEL COLOR MONITOR 21"

CABLE CARRIER KIT, 8'

ARMREST SET

This quotation shall remain valid until March 28, 2014.
All prices are F.O.B. destination.
Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 30 days after shipment or upon availability for first use by purchaser, whichever comes first.

Additional terms and conditions appear at the end of this quotation. McKesson Agreement Required ______Yes ______No
Vital Software License Agreement Required ______Yes ______No

Please return signed quotation to: Toshiba America Medical Systems, 2441 Michelle Drive, Tustin, CA 92780.

ACCEPTED AGREED AND ORDERED:

CUSTOMER REQUESTED DELIVERY DATE:

PURCHASE SIGNATURE/WHEN

TOSHIKA REP/CONTACT

DATE

ZONE SALES MANAGER

DATE
Terms & Conditions: THE PURCHASE AND ACCEPTANCE OF THE EQUIPMENT LISTED BY THIS PURCHASE ORDER IS SUBJECT TO EVALUATION FOR SAFETY AND SUITABILITY FOR INTENDED USE IN ACCORDANCE WITH NATIONALLY RECOGNIZED STANDARDS. THE EVALUATION SHALL BE CONDUCTED BY A QUALIFIED TESTING LABORATORY APPROVED BY THE COMMISSIONER OF INSURANCE OF THE STATE OF NORTH CAROLINA, OR BY ANY SPECIFIC ALTERNATIVE EVALUATION AUTHORIZED BY THE ENGINEERING DIVISION OF THE DEPARTMENT OF INSURANCE.

ORDER TO INCLUDE:

ONE EACH SERVICE MANUAL

ONE EACH OPERATOR'S MANUAL

AT NO CHARGE FirstHealth Hospitals

if shipment cannot be made at these prices, notify purchasing prior to shipping. No item may be substituted on this order without our permission. Electrical equipment used in a hospital environment must comply with NC General statute 66-23 through 66-27, Article 4.
**Vendor:** TOSHIBA AMERICA MEDICAL SYSTEMS INC  
2441 MICHELLE DR  
TUSTIN, CA 92780  
Phone: 8005211968  
Fax:  

**Ship To:** FIRSTHEALTH MOORE REGIONAL HOSPITAL  
ATTN RECEIVING  
110 PAGE ROAD NORTH  
PINEhurst, NC 28374  
GLN:  
Phone:  
Fax: 910-715-1088  

**Bill To:** ACCOUNTS PAYABLE - FHC  
FIRSTHEALTH MOORE REGIONAL HOSPITAL  
ATTN ACCOUNTS PAYABLE  
P.O. BOX 3000  
PINEhurst, NC 28374  
Phone:  
Fax: 910-715-1088  

**Vendor Code:** 767  
PO Type: CAP  
PO Status: On Order  
Customer No: 102933/8374  

**Comment:** CONTINGENT UPON BOARD AND CON APPROVAL  
PLEASE FAX 910-715-1088 OR EMAIL GBULLARD@FIRSTHEALTH.ORG CONFIRMATION  
THANKS AND HAVE A BLESSED DAY AND WEEKEND PHONE 910-715-1074  

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<th>Line</th>
<th>Vendor Catalog</th>
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<th>Mfr Catalog Contract</th>
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<th>Price Discount</th>
<th>Ext. Price Tax</th>
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<td>1 EA</td>
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<td>$1,100,000.00</td>
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**QUOTE NO:** 46248  
**SID NO:** 30012973

CONTINGENT UPON BOARD AND CON APPROVAL

**PO Sub Total:** $1,100,000.00  
**Tax Total:** $74,250.00  
**Purchase Order Total:** $1,174,250.00

**Signature(s):**

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**Print Date:** 04/02/2014 3:14PM  
**Page:** 2  
**Report ID:** PONow457  
**Total Pages Printed:** 2
PROPOSED CAPITAL COSTS

Project name: Cardiac Catheterization Replacement

Proponent: FirstHealth Moore Regional Hospital

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<tr>
<th>Site Costs</th>
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<tr>
<td>(1) Full purchase price of land</td>
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<td>Acres at $____ per acre</td>
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<td>(2) Closing costs</td>
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<td>(3) Site inspection and survey</td>
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<td>(4) Legal fees/subsoil investigation</td>
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<td>(5) Site preparation costs</td>
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<td>(6) Other (Demolition)</td>
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<td>(7) Sub-Total Site Costs</td>
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<td>(8) Cost of materials</td>
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<td>(9) Other (Specify)</td>
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<td>(10) Sub-Total Construction Contract</td>
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<tr>
<td>(11) Building purchase</td>
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<tr>
<td>(12) Fixed equipment purchase/lease</td>
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<td>(13) Movable equipment purchase/lease</td>
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<td>(15) Landscaping</td>
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<td>(16) Consultant fees</td>
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<td>(19) Other (Contingency)</td>
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<td>(20) Sub-Total Miscellaneous</td>
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| (21) TOTAL CAPITAL COST OF PROJECT | $1,284,250 |

Exhibit B
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<tr>
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<th>EXISTING EQUIPMENT</th>
<th>REPLACEMENT EQUIPMENT</th>
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<td>Type of Equipment (List Each Component)</td>
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<td>Cardiac Catheterization</td>
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<td>Manufacturer of Equipment</td>
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<td>Provider's Method of Identifying Equipment</td>
<td>Research, Quality and Price</td>
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<td>Date of Acquisition of Each Component</td>
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<td>Does Provider Hold Title to Equipment or Have a Capital Lease?</td>
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<td>Specify if Equipment Was/Is New or Used When Acquired</td>
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<td>Total Capital Cost of Project (Including Construction, etc.)</td>
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<td>$1,284,250</td>
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<tr>
<td>Total Cost of Equipment</td>
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<td>Fair Market Value of Equipment</td>
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<td>Number Days in Use/To be Used in N.C. Per Year</td>
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<td>365</td>
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<td>Type of Procedures Currently Performed on Existing Equipment</td>
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