



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

March 7, 2016

Robert A. Leandro
Parker Poe Adams & Bernstein LLP
301 Fayetteville Street
Suite 1400
Raleigh, NC 27601

Exempt from Review – Replacement Equipment

Record #: 1884
Facility Name: Lake Norman Regional Medical Center
FID #: 990475
Business Name: Lake Norman Regional Medical Center
Business #: 2357
Project Description: Replace Cardiac Catheterization Equipment
County: Iredell County

Dear Mr. Leandro:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of February 18, 2016 and subsequent emails, the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, the cardiac catheterization equipment Toshiba Infinix Select Cardiovascular System Equipment Number SEL/8.1216.000. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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



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

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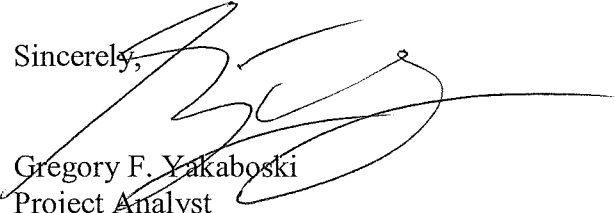
Robert A. Leandro


March 7, 2016

Page 2

It should be noted that the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,


Gregory F. Yakaboski
Project Analyst
Need


Martha J. Frisone,
Assistant Chief, Certificate of

cc: Kelli Fisk, Program Assistant, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Yakaboski, Greg

From: Leandro, Robert A. <robbleandro@parkerpoe.com>
Sent: Friday, March 04, 2016 1:41 PM
To: Yakaboski, Greg
Subject: FW: Information Needed for CON Material Compliance Letter

Greg,

Please see below.

Robert Leandro
Partner

Visit our healthcare blog:
healthlaw.parkerpoe.com



PNC Plaza | 301 Fayetteville Street | Suite 1400 | Raleigh, NC 27601
Office: 919.835.4636 | Fax: 919.834.4564 | [vcard](#) | [map](#)

From: Banks, Matthew A [mailto:Matthew.Banks@lnrmc.com]
Sent: Friday, March 04, 2016 1:38 PM
To: Leandro, Robert A.
Subject: RE: Information Needed for CON Material Compliance Letter

I can confirm that the old unit will not be used again within North Carolina without applying for a CON. The old unit is being turned into Toshiba for removal.

Matthew A. Banks | Chief Operating Officer
Lake Norman Regional Medical Center | 704-660-4055
171 Fairview Road, (PO Box 3250) Mooresville, NC 28117
Matthew.Banks@lnrmc.com
www.lnrmc.com

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Yakaboski, Greg

From: Leandro, Robert A. <robbleandro@parkerpoe.com>
Sent: Friday, March 04, 2016 10:46 AM
To: Yakaboski, Greg
Subject: Lake Norman Regional

Greg,

To follow up on your request, the Cardiac Cath replacement machine my client is purchasing is a Toshiba Infinix Select Cardiovascular System Equipment Number SEL/8.1216.000.

Thank you for your help with this, let me know if you have any additional questions.

Robb

Robert Leandro

Partner

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STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number F-6380-01

FID #990475

ISSUED TO: Mooresville Hospital Management Associates, Inc.
d/b/a Lake Norman Regional Medical Center
P.O. Box 3250
Mooresville, NC 28117

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)g. 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: Mooresville Hospital Management Associates, Inc. d/b/a Lake Norman Regional Medical Center shall dedicate the existing fixed angiography equipment, a Siemens Multistar Plus/D, as shared fixed cardiac catheterization equipment/Iredell County

CONDITIONS: See Reverse Side

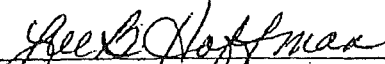
PHYSICAL LOCATION: Lake Norman Regional Medical Center
171 Fairview Road
Mooresville, NC 28117

MAXIMUM CAPITAL EXPENDITURE: \$184,260

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: July 31, 2002

This certificate is effective as of the 17th day of April, 2002.



Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. Mooresville Hospital Management Associates, Inc. d/b/a Lake Norman Regional Medical Center shall materially comply with all representations made in the certificate of need application except as modified by the supplemental information received August 29, 2001. In those instances in which representations conflict, Mooresville Hospital Management Associates, Inc. d/b/a Lake Norman Regional Medical Center shall materially comply with the last-made representation.
2. Upon completion of the project, Mooresville Hospital Management Associates, Inc. d/b/a Lake Norman Regional Medical Center shall operate no more than one unit of shared fixed cardiac catheterization equipment.
3. Mooresville Hospital Management Associates, Inc. d/b/a Lake Norman Regional Medical 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.

TIMETABLE

Financing

Obtaining funds necessary to undertake project _____ April 15, 2002

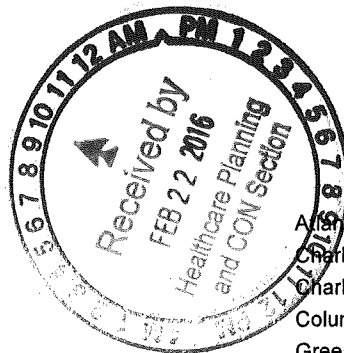
Acquisition of Medical Equipment

Ordering equipment _____ May 1, 2002

Arrival of equipment _____ June 15, 2002

Operation of equipment
as shared fixed cardiac catheterization equipment _____ July 15, 2002

Offering of services _____ July 15, 2002



Robert A. Leandro
Partner
 Telephone: 919.835.4636
 Direct Fax: 919.835.4614
 robbleandro@parkerpoe.com

Atlanta, GA
 Charleston, SC
 Charlotte, NC
 Columbia, SC
 Greenville, SC
 Raleigh, NC
 Spartanburg, SC

February 18, 2016

Email received 2/18/16

VIA U.S. AND ELECTRONIC MAIL

Martha Frisone
 Assistant Chief
 Healthcare Planning and Certificate of Need Section
 North Carolina Department of Health and Human Services
 2704 Mail Service Center
 Raleigh, NC 27699-2704
Martha.Frisone@dhhs.nc.gov

Re: Request for No Review Determination

Dear Ms. Frisone:

This letter is intended to provide notice to the Certificate of Need Section (“CON”) that Lake Norman Regional Medical Center (“Lake Norman”) is planning to replace its existing cardiac catheterization equipment. The replacement equipment, including the costs of activities essential to making the equipment operational, is estimated to cost approximately \$2,100,000.00.

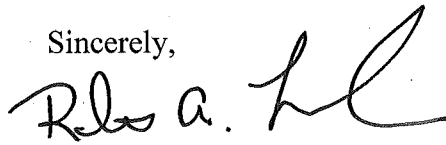
The proposed replacement equipment meets the exemption requirements set forth in N.C. Gen. Stat. § 131E-184(f). The equipment being replaced is located in the main building of Lake Norman Regional, which is the hospital’s “main campus” as defined by N.C. Gen. Stat. § 131E-176-14(n). The new equipment will be placed in the same location within the main building of the medical center. *See* attached letter. The equipment being replaced was also the subject of previous CON review by the Agency. A CON was issued for the existing cardiac catheterization equipment on April 17, 2002 (F-6380-01). *Id.*

Lake Norman requests that the CON Section issue a written determination confirming that replacing this equipment on its main campus is not subject to CON review under N.C. Gen. Stat. § 131E-184(f).

February 18, 2016
Page 2

I greatly appreciate your attention to this matter. Please call me if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "R. A. Leandro". The signature is fluid and cursive, with the first name "R." and last name "Leandro" clearly distinguishable.

Robert A. Leandro

Enclosures



February 18, 2016

VIA U.S. MAIL AND ELECTRONIC MAIL

Martha Frisone
Assistant Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704
Martha.Frisone@dhhs.nc.gov

Dear Ms. Frisone:

By this letter, Lake Norman Regional Medical Center is providing notice to the Healthcare Planning and Certificate of Need Section ("CON Section") that it plans to replace its existing cardiac catheterization equipment, pursuant to N.C. Gen. Stat. § 131E-184(f). Lake Norman is seeking this exemption because the cost of the replacement equipment exceeds \$2 million.

Under the statute, in order to meet the exemption, Lake Norman must provide documentation demonstrating that the criteria set forth in N.C. Gen. Stat. § 131E-184(f) has been met. I can confirm that this cardiac catheterization equipment was obtained by Lake Norman as a result of the issuance of a CON on April 17, 2002 (F-6380-01).

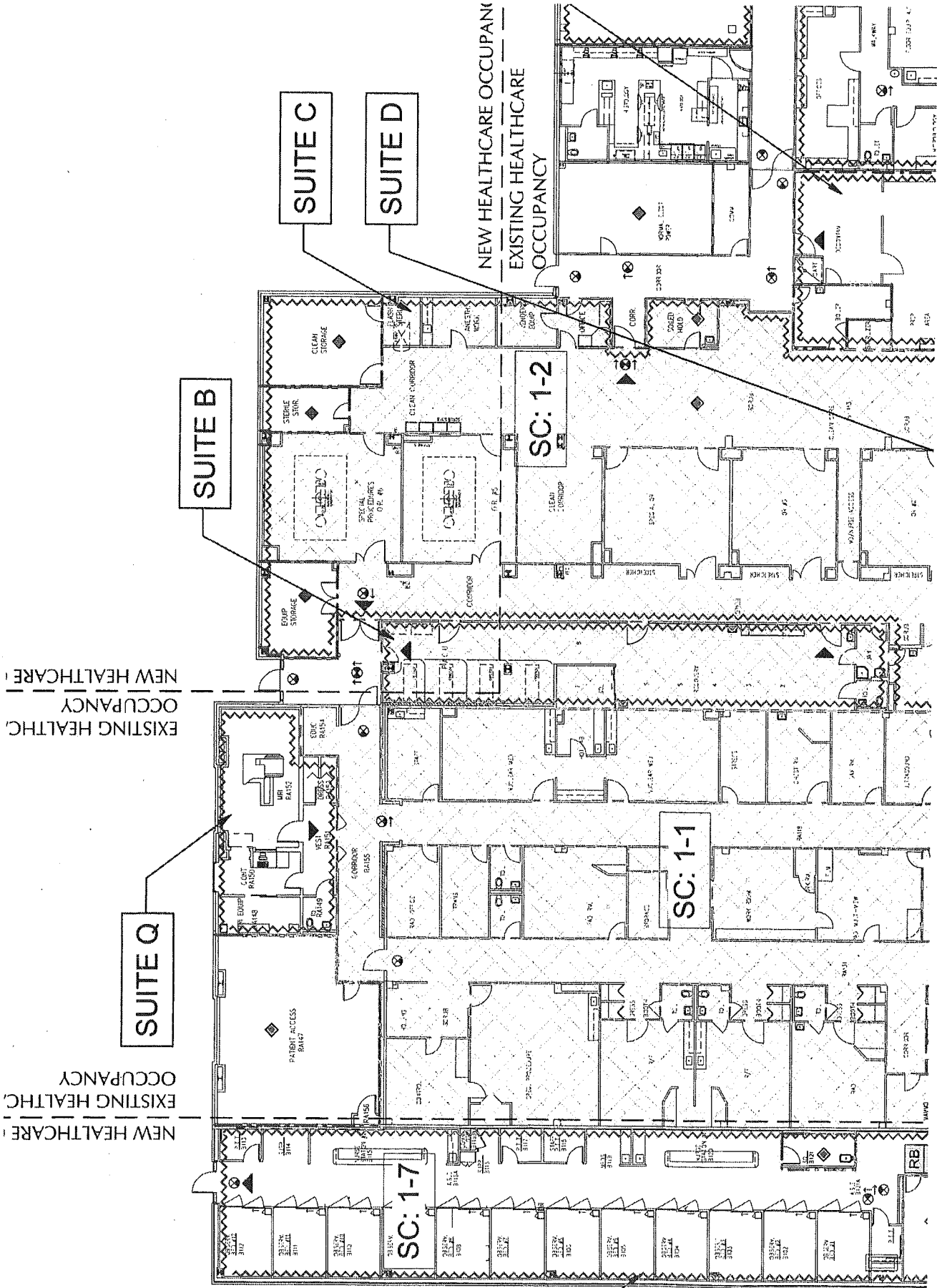
In addition, I can confirm that the current cardiac catheterization equipment and the replacement equipment will be located in the main building of Lake Norman Regional Medical Center. Lake Norman Regional Medical Center provides clinical patient services in the main building of the hospital. We also exercises financial and administrative control over the facility from this building. Please find enclosed a map of the hospital showing the location of the cardiac catheterization equipment.

Sincerely,

A handwritten signature in black ink that reads "M.A. Banks".

Matthew A. Banks

Enclosures



NEW HEALTHCARE
OCCUPANCY

NEW HEALTHCARE
OCCUPANCY

SUITE Q

SUITE B

SUITE C

SUITE D

A

SC: 1-2

SC: 1-1

SC: 1-7

NEW HEALTHCARE OCCUPANCY
EXISTING HEALTHCARE
OCCUPANCY

NEW HEALTHCARE
OCCUPANCY

NEW HEALTHCARE
OCCUPANCY

