



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 19, 2024

Anthony Brett

Anthony.brett@wbd-us.com

Exempt from Review – Replacement Equipment

Record #: 4355

Date of Request: January 4, 2024

Facility Name: Carolina Lithotripsy-Mobile: Eastern NC

Business Name: Carolina Lithotripsy, a Limited Partnership

Business #: 2133

Project Description: Replace a mobile lithotripter and refurbish support vehicle serving eastern NC

County: Multi-County

Dear Mr. Brett:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the mobile Storz F2 Lithotripter (Serial #OR.1341) to replace the mobile Siemens Variostar Lithotripter (Serial #6010). This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Micheala Mitchell

Chief

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

January 4, 2024

Micheala Mitchell, Chief, Certificate of Need
Healthcare Planning and Certificate of Need
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603
micheala.mitchell@dhhs.nc.gov

Womble Bond Dickinson (US) LLP

One West Fourth Street
Winston-Salem, NC 27101

t: 336.721.3600
f: 336.721.3660

Via E-mail Only

Re: Notice of Replacement Equipment exempt pursuant to N.C. Gen. Stat. § 131E-184(a)(7) - Replacement of Mobile Lithotripter - Carolina Lithotripsy, a Limited Partnership ("Carolina Lithotripsy")

Anthony Brett
Partner
Direct Dial: 336-721-3620
Direct Fax: 336-733-8331
E-mail: Anthony.Brett@wbd-us.com

Dear Ms. Mitchell:

Carolina Lithotripsy currently operates a Siemens Variostar lithotripter (Serial Number 6010) which is approaching the end of its useful life as one of its two mobile lithotripters in North Carolina. Carolina Lithotripsy plans to replace this Siemens mobile lithotripter with a new Storz F2 lithotripter (Serial Number OR.1341).

The replacement lithotripter described in the preceding paragraph complies with all requirements of N.C. Gen. Stat. §131E-176(22a) and 10A N.C.A.C. 14C.0303 to constitute replacement equipment. Therefore, the replacement Storz lithotripter would be exempt from CON review pursuant to § 131E-184(a)(7). The requirements to qualify as replacement equipment and the facts concerning the replacement Storz lithotripter in this instance are discussed below.

First, all costs at fair market value that are necessary for the operation of the replacement Storz lithotripter are less than \$3 million¹. There are two components of the costs, which consist of the Storz lithotripter and the transportation vehicle for it. The Storz lithotripter's all-inclusive cost is \$474,676², and Carolina Lithotripsy will refurbish its used truck for its transportation at a cost of \$19,000.

Second, the Storz lithotripter is comparable equipment to the Siemens lithotripter as the replacement lithotripter does not perform any function that is not currently performed by the existing lithotripter.

¹ While not yet in published versions of Section 131E-176(22a), the amount was increased from \$2 million to \$3 million (plus an annual CPI increase) effective March 27, 2023 by Section 3.1(a) of S.L. 2023 – 7 (HB76).

² If Carolina Lithotripsy chooses to acquire the Storz lithotripter with a lease/purchase contract, its total cost over sixty months would be \$591,909.40.



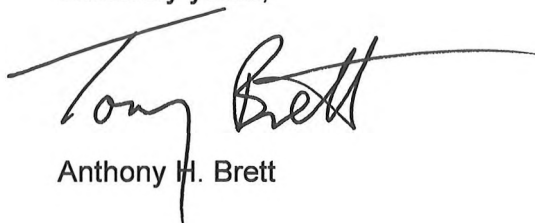
Third, the Siemens lithotripter has been in use by Carolina Lithotripsy since 2014, and it has been in continuous regular use far exceeding the regulatory volume minimum of ten procedures in the twelve-month period preceding this notice.

Fourth, the Siemens lithotripter will not be used in North Carolina once the replacement Storz lithotripter has begun service. The Siemens lithotripter will be “cannibalized” for parts to maintain the operation of other mobile lithotripters only.

Based upon the information provided herein, please confirm that Carolina Lithotripsy’s replacement equipment is exempt from certificate of need review.

If there are any questions, please let me know at your earliest convenience. Thank you for your cooperation.

Sincerely yours,

A handwritten signature in black ink that reads "Tony Brett". The signature is fluid and cursive, with a long horizontal line extending from the end of the name.

Anthony H. Brett

cc: Lisa.Pittman@dhhs.nc.gov (Assistant Chief, Certificate of Need)

From: [Pittman, Lisa](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] RE: Please see the attachment.
Date: Thursday, January 4, 2024 9:08:59 AM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)
[WBD-Scan - 2024-01-03 18.10.28.pdf](#)

If Micheala hasn't already forwarded this to you, please add to the Log and assign to Greg.

Thanks!

Lisa Pittman
Assistant Chief
Division of Health Service Regulation, Healthcare Planning & CON Section
NC Department of Health and Human Services

Office: 919-855-3989 *I work from home and in the office. Email is the best way to contact me.*
Lisa.Pittman@dhhs.nc.gov

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From: Brett, Anthony <Anthony.Brett@wbd-us.com>
Sent: Thursday, January 4, 2024 8:58 AM
To: Pittman, Lisa <lisa.pittman@dhhs.nc.gov>
Cc: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Subject: [External] RE: Please see the attachment.

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.

Ms. Pittman, I apologize. I entered your email address incorrectly, so you did not receive my email below.

From: Brett, Anthony <Anthony.Brett@wbd-us.com>
Sent: Thursday, January 4, 2024 8:50 AM
To: micheala.mitchell@dhhs.nc.gov

Cc: lisa.pittman@dhhs.nc.gov

Subject: Please see the attachment.

Anthony Brett

Partner

Womble Bond Dickinson (US) LLP

d: [336-721-3620](tel:336-721-3620)

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