



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

December 7, 2021

Anthony Brett  
[Anthony.brett@wbd-us.com](mailto:Anthony.brett@wbd-us.com)

**Exempt from Review – Replacement Equipment**

**Record #:** 3753  
**Date of Request:** November 29, 2021  
**Facility:** Carolina Lithotripsy- Mobile: Eastern NC  
**Business Name:** Carolina Lithotripsy, a Limited Partnership  
**Business #:** 2133  
**Project Description:** Replace a mobile lithotripter and 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 Storz F2 lithotripter (Serial Number OR-1470) to replace the Siemens Modularis Variostar-1157200 Serial #6008. 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

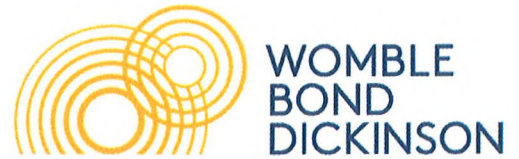
Micheala Mitchell  
Chief

cc: Construction 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  
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**November 29, 2021**

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  
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Womble Bond Dickinson (US) LLP

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Winston-Salem, NC 27101

t: 336.721.3600  
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**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  
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Dear Ms. Mitchell:

Carolina Lithotripsy currently operates a Siemens Variostar lithotripter (Serial Number 6008) 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-1470).

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 \$2 million. 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 \$463,012.00, and Carolina Lithotripsy will acquire a used truck for its transportation at an approximate cost of \$65,000.00 although the exact cost has not been determined at this time. In any event, the combined cost of the two components is well below \$2 million. While Carolina Lithotripsy has the option to lease both components, the fair market value determination would be based upon the actual costs of the two components. But even if both components were leased, the components total costs for 60 months would also be well below \$2 million (\$511,399.98 for the Storz lithotripter and \$120,000.00 for the truck).

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.




Third, the Siemens lithotripter has been in regular use by Carolina Lithotripsy since 2014, and it has been in continuous regular use far exceeding the regulatory volume minimum 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,



Anthony H. Brett

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