January 18, 2022

Bill Schiff
bill.schiff@dm.duke.edu

Exempt from Review – Replacement Equipment

Record #: 3788
Date of Request: January 12, 2022
Facility Name: Kernodle Clinic Burlington
FID #: 210087
Business Name: Private Diagnostic Clinic, PLLC
Business #: 1478
Project Description: Replace existing equipment
County: Alamance

Dear Mr. Schiff:

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 PulmOne pulmonary function testing equipment to replace the VIASYS Model 22E pulmonary function testing equipment, Serial #TMI-000540-A. 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,

Celia C. Inman
Project Analyst

Micheala Mitchell
Chief
Martha, please add this additional information to the Kernodle Exemption request currently in my folder.

Thanks,

Celia C. Inman
Project Analyst, Certificate of Need
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services

Office: 919-855-3873 (currently, due to COVID, I am in the office Mondays, Tuesdays, and Wednesdays and work from home on Thursdays and Fridays. I can best be reached by email.)
Celia.Inman@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704

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Hi Ms. Inman,

Please find attached the Replacement Equipment Comparison Form and the quote you requested.

If you need anything else, please let me know.
Best,

Michaela McMorris, MHA  
Planning Analyst  
Private Diagnostic Clinic, PLLC  
Duke Health  
919-668-6607  
michaela.mcmorris@duke.edu

From: Inman, Celia C <celia.inman@dhhs.nc.gov>  
Sent: Wednesday, January 12, 2022 4:22 PM  
To: Michaela McMorris <michaela.mcmorris@duke.edu>  
Cc: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Sara Holleran <sara.holleran@duke.edu>; Karin Sandlin <ksandlin@claritysservices.com>  
Subject: RE: [External] Kernodle Clinic Burlington Material Compliance Request

Ms. McMorris and Mr. Schiff:  
In order to evaluate your exemption request for replacement equipment, the attached form needs to be filled out and returned to me. A quote verifying the cost of the new equipment would also be helpful. I will be watching for the completed form.  
Thanks,

Celia C. Inman  
Project Analyst, Certificate of Need  
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section  
NC Department of Health and Human Services

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### PulmOne Advanced Medical Devices

#### Account Name
Duke Medical - Kernodle Clinic West

#### Contact Name
Fuad Aleskerov

#### Phone
404-353-8944

#### Billing Address
1234 Huffman mill Rd
Burlington, NC 27215
USA

#### Prepared By
Patrick Sweeney

#### Email
patrick@pulm-one.com

### Product

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-Liter Calibration syringe</td>
<td>1.00</td>
</tr>
<tr>
<td>DLCO Gas Regulator</td>
<td>1.00</td>
</tr>
<tr>
<td>MB+ Extended Warranty - 3-4-4</td>
<td>1.00</td>
</tr>
<tr>
<td>MiniBox+ Cart with Power Supply mount and E-size cylinder gas tank holder</td>
<td>1.00</td>
</tr>
<tr>
<td>MiniBox+™ Starter Kit</td>
<td>1.00</td>
</tr>
<tr>
<td>Shipping, installation, onsite training, 25 filters, software upgrades and 1 year manufacturer's warranty</td>
<td>1.00</td>
</tr>
</tbody>
</table>

#### Payment Terms
Other

#### Total Price
USD 45,545.00

#### Deal Discount
USD 8,000.00

#### Deal Total
USD 37,545.00

#### Grand Total
USD 37,545.00

---

PulmOne Signature: __________________

Customer Signature: __________________

Date: ________________
1. Acceptance of Terms: PulmOne USA Inc. (“PulmOne”) agrees to sell to the person (“Customer”) named in the purchase order (the “Order”) those products and/or services referenced in the Order (“Products” and “Services” respectively), on and subject to these terms and conditions. No Order shall be binding on PulmOne until accepted by PulmOne in writing.

2. Price and Taxes: Prices in the Order do not include applicable value added, excise, sales, use, transfer, or other similar taxes which shall be borne solely by Customer.

3. Payment Terms; Default: All amounts must be paid within the period referenced in the Order. Customer will pay default interest on all outstanding amounts due under any Order at a rate of 2.0% per month, compounded simply (“Default Interest”). Should any amount owing and payable by Customer in respect of a Product be delayed by 30 days or more, then PulmOne shall be entitled, by notice to Customer, to terminate the Order, in which case, the following shall apply: (i) Customer must return the Product to PulmOne, at Customer’s sole expense and risk, in the condition in which it was first delivered to Customer, together with all related packaging; (ii) to the extent PulmOne determines, in its sole discretion, that the Product is no longer in the condition in which it was originally delivered to Customer, then PulmOne shall be entitled to impose a fee on Customer, which Customer must pay on demand, up to the price of the Product; (iii) Customer will be required to pay to PulmOne, on demand, all costs and expenses (including reasonable attorney fees) in enforcing PulmOne’s rights hereunder, plus a handling fee in the amount of $1,500 (plus applicable taxes); (iv) Default Interest will continue to accumulate until Customer’s obligations under this provision have been fully complied with; and (v) Customer shall not be entitled to a refund of any amounts previously paid by Customer in respect of the Product.

4. Title and Risk of Loss: Title to the Products shall pass to Customer after and subject to full payment for the Products is received by PulmOne, however risk of loss shall pass to the Customer immediately upon delivery of the Products.

5. Acceptance and Inspection: All Products delivered must be examined by the Customer promptly upon receipt. Customer shall notify PulmOne in writing within ten (10) days after such receipt of any discrepancies between Products received and those ordered by Customer and any apparent defects or damage to the Products (inspection claims). PulmOne shall not be obligated to consider inspection claims made after such 10 day period. If an Order includes initial demonstration of Product functionality by PulmOne, Customer shall be deemed to accept the Products when functional testing by PulmOne demonstrates that a Product conforms to the specifications in such Product’s operator manual.

6. Limited Warranty: All Products are warranted to be free of material defects in materials and workmanship for a period of 12 months beginning from the date Customer received the delivery of the Products (the “Warranty Period”). Customer’s sole remedy in respect of a defective Product shall be to return the defective Product to PulmOne and receive a replacement Product (fixed or new) in return, or a credit in respect of the defective Product, at PulmOne’s sole discretion. The cost of shipment of defective Products to PulmOne shall be for the account of Customer, and the cost of return of the replacement Product shall be for the account of PulmOne. Without derogating from the foregoing, it is hereby clarified that this limited warranty does not extend to: (i) nonconformities, defects or errors in the Products due to accident, abuse, misuse or negligent use of the Products or use in other than a normal and customary manner and in normal and customary environmental conditions, or failure to follow prescribed operating maintenance procedures, (ii) defects, errors or nonconformities in the Products due to modifications, alterations, additions or Product changes not made or authorized to be made by PulmOne, (iii) normal wear and tear, or (iv) damage caused by force of nature or act of Customer or any third party. The Warranty Period may be extended by the Customer by payment of an additional fee to PulmOne for such extended period, in an amount set by PulmOne from time to time.

7. Intellectual Property Rights. All intellectual property and other rights with respect to the Products, including, but not limited to, all patents, trademarks, copyrights, service marks, trade names, technology, know how, moral rights and trade secrets, all applications for any of the foregoing, and all permits, grants and licenses or other rights relating to the Products, both registered and unregistered, owned and/or otherwise used by PulmOne and all goodwill related thereto (hereinafter, referred to as the “IP Rights”) are and shall remain at all times the sole and exclusive property of PulmOne. Customer will not have or acquire any right, title or interest in or otherwise become entitled to any IP Rights by taking delivery of, making payment for or otherwise using the Products. Customer must not reverse-engineer the Products or attempt to do so, or allow any person or entity to do so.

8. Services and Support: PulmOne provides standard maintenance service, repairs and support for the Product during the Warranty Period at no additional charge to the Customer. These Services include telephone technical support, hardware repairs, and software bug fixes. After the Warranty Period, such maintenance, repair, and support services may be provided by PulmOne at its standard service rates. PulmOne shall perform the maintenance and support services in a reasonable timely, professional, and workmanlike manner using trained and qualified personnel capable of performing such services in accordance with standards used in the industry.

9. Limitations of liability: The total cumulative liability of PulmOne arising out of or in connection with any Product Ordered by Customer shall be limited to the purchase price paid by Customer for such Product. In no event shall PulmOne be liable for indirect, incidental, special,
consequential, or punitive damages, of any nature or kind whatsoever and under any theory of law (whether in contract, tort, or otherwise),
including but not limited to loss of anticipated profits, loss of revenue, loss of production, loss of business opportunity, downtime, loss of use of
equipment or any installation, system or facility into which PulmOne’s Products may be located, even if advised of the possibility of such
damages in advance, and Customer will hold PulmOne harmless from and against any and all such liability in excess of this amount. PulmOne
shall not be liable for any latent defects or any other defects that might appear after the lapse of the Warranty Period. Customer’s sole and
exclusive remedies for any damages or loss in any way connected with the provision of Services, shall be at PulmOne’s option; (i)
re-performance of the relevant Services; or (ii) return of an appropriate portion of any payment made by Customer with respect to the
applicable portion of the Services.
10. Governing Law. The Order and these terms and conditions Order shall be governed by and construed in accordance with the laws of the
State of Israel. The parties agree to submit any dispute connected with or arising under any Order to the exclusive jurisdiction of the competent
courts in New York city, NY.
## EQUIPMENT COMPARISON

<table>
<thead>
<tr>
<th></th>
<th>EXISTING EQUIPMENT</th>
<th>REPLACEMENT EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Equipment</td>
<td>Pulmonary Function Testing</td>
<td>Pulmonary Function Testing</td>
</tr>
<tr>
<td>Manufacturer of Equipment</td>
<td>VIASYS</td>
<td>PulmOne</td>
</tr>
<tr>
<td>Tesla Rating for MRIs</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Model Number</td>
<td>22E</td>
<td>MiniBox+</td>
</tr>
<tr>
<td>Serial Number</td>
<td>TMI-000540-A</td>
<td>pending</td>
</tr>
<tr>
<td>Provider’s Method of Identifying Equipment</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Specify if Mobile or Fixed</td>
<td>Fixed</td>
<td>Fixed</td>
</tr>
<tr>
<td>Mobile Trailer Serial Number/VIN #</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Mobile Tractor Serial Number/VIN #</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Date Acquired</td>
<td>2008</td>
<td>NA</td>
</tr>
<tr>
<td>Does Provider Hold Title to Equipment or Have a Capital Lease?</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Specify if Equipment Was/Is New or Used When Acquired</td>
<td>New</td>
<td>NA</td>
</tr>
<tr>
<td>Total Capital Cost of Project (Including Construction, etc.) &lt;Use Attached Form&gt;</td>
<td>NA</td>
<td>$37,545</td>
</tr>
<tr>
<td>Total Cost of Equipment</td>
<td>$28,400</td>
<td>$37,545</td>
</tr>
<tr>
<td>Fair Market Value of Equipment</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Net Purchase Price of Equipment</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Locations Where Operated</td>
<td>Kernodle Clinic Burlington</td>
<td>Kernodle Clinic Burlington</td>
</tr>
<tr>
<td>Number of Times Existing Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice</td>
<td>430</td>
<td>NA</td>
</tr>
<tr>
<td>Type of Procedures Currently Performed on Existing Equipment</td>
<td>Lung Function Tests</td>
<td>NA</td>
</tr>
<tr>
<td>Type of Procedures New Equipment is Capable of Performing</td>
<td>NA</td>
<td>Lung Function Tests</td>
</tr>
</tbody>
</table>

Date of last revision: 12/4/2020
Hello Ms. Inman,

Please see the attached request for material compliance regarding CON Project I.D. #G-12015-21.

If you have any questions, please let me know.

Best,

Michaela McMorris, MHA
Planning Analyst
Private Diagnostic Clinic, PLLC
Duke Health
919-668-6607
michaela.mcmorris@duke.edu

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Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.
January 12, 2022

Via Electronic Mail

Ms. Micheala Mitchell
Ms. Celia Inman
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC  27626-0530

RE:   Replacement of PFT Equipment at Kernodle Clinic Burlington/ Alamance County / FID #210087

Dear Ms. Mitchell:

The purpose of this letter is to notify the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) that Private Diagnostic Clinic, PLLC (PDC) plans to replace pulmonary function testing (PFT) equipment located in an existing diagnostic center. PDC requests a determination that the respective replacement is exempt from review because it falls within the definition of NCGS § 131E-184(a)(7) and the regulations set out in 10A NCAC 14C .0303.

Background

PDC received a Certificate of Need (CON) on May 11, 2021 to develop a new diagnostic center at Kernodle Clinic Burlington with x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy, and pulmonary function testing in Alamance County, CON Project I.D. # G-12015-21. The project involved the existing medical diagnostic at Kernodle Clinic Burlington and did not involve the acquisition of any new equipment or services. Because all the diagnostic equipment existed and was already in operation, the cost of the PFT equipment was not included in the approved project’s capital expenditures in Section Q (Form F.1) of the application. PDC has developed the project as previously approved by the Agency and in conformance with all the CON conditions.

Replacement Equipment

PDC intends to replace the PFT equipment located at Kernodle Clinic Burlington. The existing PFT equipment is over 13 years old and has exceeded its useful life. The manufacturer will no longer guarantee parts for the equipment. PDC has been using a loaner computer for over a year just to keep the current system running. PDC intends to replace the existing PFT equipment in the same location with new PFT equipment, which is comparable to our existing equipment in terms of function and purpose. The existing PFT equipment will be removed from PDC when the replacement equipment is installed.

Pursuant to NCGS § 131E-184(a): “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 costs 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.

10A NCAC 14C.0303 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.

The replacement of PFT equipment at PDC falls within the parameters of this exemption. Specifically:

1. The equipment being replaced is currently in use at PDC.
2. The cost to acquire and install the replacement PFT equipment is $37,545. A copy of the equipment quote is available upon request.
3. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be traded into the vendor.
4. 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.
5. PDC will not acquire any other major medical equipment or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176(16) as part of this project.
6. The project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the replacement equipment being acquired.

PDC respectfully requests that the Division of Health Service Regulation make a determination that replacement of the PFT equipment, as proposed herein, does not constitute new institutional health services and is thus exempt from certificate of need review.

Material Compliance

PDC believes that replacement of the existing PFT equipment will not constitute a material change for purposes of N.C. Gen. Stat. §131E-181(a) and will otherwise materially comply with the representations in Project ID# G-12015-21. PDC hereby certifies that:

1. It is not proposing to materially change the scope of the approved diagnostic center, which includes the existing x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy, and pulmonary function testing.
2. The replacement of existing PFT equipment will not result in an increase of greater than 115% of the approved project capital cost. The existing PFT equipment was acquired in 2009 thus the cost of the equipment was not included in the approved project’s capital expenditures in Section Q (Form F.1) of the application.

3. It will continue to comply with all the CON conditions listed on the CON (see Exhibit 1).

For these reasons, PDC believes that the replacement of Kernodle Clinic Burlington’s existing PFT equipment does not constitute a change in the scope of the project and would not violate N.C. Gen. Stat. 131E-181(a) or any of the rules of the North Carolina Department of Health and Human Services.

Please contact me at 919.668.1823 or bill.schiff@duke.edu regarding any questions concerning this request.

Sincerely,

[Signature]

Bill Schiff
Vice President, Strategic Services & Network Development
Private Diagnostic Clinic, PLLC
Exhibit 1: Certificate of Need, Project I.D. # G-12015-21
State of North Carolina
Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need
for
Project ID #: G-12015-21
FID #: 210087

ISSUED TO: Private Diagnostic Clinic, PLLC

Pursuant to G.S. 131E-177(6), the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the certificate holder) to develop the project described below. The certificate holder shall develop the project in a manner consistent with the representations in the application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by G.S. 131E-189(a). The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by G.S. 131E-176(16)c. The certificate holder shall not transfer or assign this certificate to any other person except as provided in G.S. 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 G.S. 131E-189 for any of the reasons provided in that section.

SCOPE: Develop a new diagnostic center at Kernodle Clinic to include x-ray, ultrasound, EEG, nuclear camera, DEXA, Topcon Eye Retina scanner, scrambler therapy and pulmonary function testing/ Alamance County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Kernodle Clinic Burlington
1234 Huffman Mill Road
Burlington, NC 27215

CAPITAL EXPENDITURE: $50,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: October 1, 2021

This certificate is effective as of May 11, 2021

Lisa Pittman, Acting Chief, CON
CONDITIONS:

1. Private Diagnostic Clinic, PLLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

2. The certificate holder shall develop a new diagnostic center with existing diagnostic equipment, as designated in the application.

3. Progress Reports:
   a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
   b. The certificate holder shall complete all sections of the Progress Report form.
   c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
   d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on October 1, 2021. The second progress report shall be due on January 1, 2022 and so forth.

4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
   a. Payor mix for the services authorized in this certificate of need.
   b. Utilization of the services authorized in this certificate of need.
   c. Revenues and operating costs for the services authorized in this certificate of need.
   d. Average gross revenue per unit of service.
   e. Average net revenue per unit of service.
   f. Average operating cost per unit of service.

7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on April 21, 2021.

Timetable

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Date mm/dd/yyyy</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Services Offered</td>
<td>09/01/2021</td>
</tr>
<tr>
<td>17 First Annual Report Due*</td>
<td>03/31/2023</td>
</tr>
</tbody>
</table>
Please log this request.

Thanks,

Celia C. Inman
Project Analyst, Certificate of Need
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services

Office: 919-855-3873 (currently, due to COVID, I am in the office Mondays, Tuesdays, and Wednesdays and work from home on Thursdays and Fridays. I can best be reached by email.)
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Hello Ms. Inman,

Please see the attached request for material compliance regarding CON Project I.D. #G-12015-21.

If you have any questions, please let me know.