

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 26, 2025

Taylor Spell tspell2@capefearvalley.com

Exempt from Review – Replacement Equipment

Record #: 4928

Date of Request: September 17, 2025

Facility Name: Cape Fear Valley Medical Center

FID #: 030360

Business Name: Cumberland County Hospital System, Inc.

Business #: 578

Project Description: Replace CyberKnife linear accelerator

County: Cumberland

Dear Mr. Spell:

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(f). Therefore, you may proceed to acquire without a certificate of need the Varian Ethos linear accelerator to replace the Accuray E2E/G4 CyberKnife linear accelerator. 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,

Cynthia Bradford Project Analyst

Micheala Mitchell Chief

Micheala Mitchell

cc: Acute and Home Care Licensure and Certification Section, DHSR

Radiation Protection 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

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873



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MOBILE INTEGRATED HEALTHCARE

SLEEP CENTER

September 17, 2025

Ms. Tanya Saporito

Project Analyst, Healthcare Planning & Certificate of Need Section

Division of Health Service Regulation

N.C. Department of Health and Human Services

2704 Mail Center Service Raleigh, NC 27699-2704

RE: Replacement of CyberKnife Linear Accelerator at Cape Fear Valley Medical Center/ Cumberland County

Ms. Saporito:

The purpose of this letter is to give the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") prior written notice pursuant to NCGS § 131E-184(f) that Cape Fear Valley Medical Center ("CFVMC") plans to replace its CyberKnife linear accelerator located on the hospital's main campus.

The existing equipment is situated in the CFVMC cancer center, which is located on the hospital's main campus. The equipment has been in service at CFVMC for 14 years and has exceeded its useful life. CFVMC intends to replace the CyberKnife linear accelerator in the same location with a new Varian Ethos linear accelerator. The existing linear accelerator will be removed from CFVMC and returned to the vendor when the replacement linear accelerator is installed.

Pursuant to NCGS § 131 E-184(f): "The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the monetary threshold set forth in G.S. 131E-176(22a) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.



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The replacement of the CyberKnife linear accelerator at CFVMC falls within the parameters of this exemption. Specifically:

- 1. The equipment being replaced is currently located on the CFVMC main campus.
- 2. A CON was issued for the linear accelerator that will be replaced (M-7750-06).
- 3. This letter serves as prior written notice to the Department.

Both the Varian Ethos and the Accuray CyberKnife are linear accelerators used for advanced radiation therapy. Please see Attachment A for a copy of the replacement equipment comparison table, which demonstrates the proposed linear accelerator is comparable to the equipment being replaced.

The estimated project cost for the replacement linear accelerator is \$6,527,015, which includes equipment and renovations to accommodate the replacement equipment. Attachment B contains a copy of the estimated capital cost.

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

Please contact me at 910.615.7529 or tspell2@capefearvalley.com regarding any questions concerning this request.

Sincerely,

Taylor Spell, CPA

Taylor Spell

Senior Finance & Strategic Planning Analyst

Cape Fear Valley Health System

ATTACHMENT A REPLACEMENT EQUIPMENT COMPARISON TABLE

	Cyberknife
Type of Existing Equipment	Cyberknife (Linear Accelerator)
Manufacturer of Existing Equipment	Accuray
CON Project ID, if applicable	M-7750-06
Tesla Rating for MRI Being Replaced	N/A
Model Number - Existing	E2E/G4
Serial Number - Existing	CK262
Provider's Method of Identifying Equipment	Vendor SN
Specify if Mobile or Fixed	Fixed
Mobile Trailer Serial Number / VIN #	N/A
Mobile Tractor Serial Number / VIN #	N/A
Date Acquired	5/23/2011
Does Provider Hold Title to Equipment or Have a Capital Lease?	Own
Specify if Equipment Was/Is New or Used When Acquired	New
Total Capital Cost of Project (Including Construction, etc.)	\$6,527,015
Total Cost of Equipment	\$5,801,652
Location Where Operated	Cape Fear Valley Medical Center
	Equipment is used on a case by case
	basis. Equipment is approaching end of
Number of Times Equipment was Used to Provide a Health Service during the 12	life and has frequently experienced
months prior to the Date of the Written Notice	downtime in the last 12 months
Type of Procedures Currently Performed on Existing Equipment	SRS/SBRT
Type of Procedures New Equipment is Capable of Performing	SRS/SBRT

New Equipment

Manufacturer of New Equipment	Varian
Tesla Rating for New MRI	N/A
Model Number - New Equipment	Ethos LINAC
Serial Number - New Equipment	TBD

Attachment B Replacement Equipment: Capital Cost

Projected Capital Cost Form:	Cyberknife
Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction / Renovation Contract (s)	\$725,363
Landscaping	
Architect / Engineering Fees	
Medical Equipment	\$5,801,652
Non-Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (Specify)	
TOTAL CAPITAL COSTS	\$6,527,015

From: **Taylor Spell** Tanya, Saporito To:

Sandy Godwin; Stancil, Tiffany C Cc:

[External] CFVMC Cyberknife Replacement - Exemption Request Subject:

Date: Wednesday, September 17, 2025 10:30:35 AM

Attachments: image001.png

CFVMC CyberKnife Replacement Letter.pdf

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.

Hi Tanya,

Happy Wednesday! I have attached an exemption request for the replacement of the Cyberknife located on the campus of Cape Fear Valley Medical Center. Please let me know if you have any questions.

Have a great day!

Thank you,

Taylor

Taylor Spell, CPA | Senior Finance & Strategic Planning Analyst

Cape Fear Valley Health System | 101 Robeson Street, Suite 303 | Fayetteville, NC 28301 Office: 910-615-7529 | tspell2@capefearvalley.com

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