



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

CORRECTED LETTER

January 12, 2015

Mr. Anthony H. Brett
Womble, Carlyle, Sandridge & Rice
One West Fourth Street
Winston-Salem, NC 27101

Exempt from Review - Replacement Equipment

Facility: Fayetteville Lithotripters Limited Partnership – Virginia I
Project Description: Replace existing mobile lithotripsy unit
County: Chowan, Dare and Pasquotank Counties

Dear Mr. Brett:

In response to your letter of November 24, 2014 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Lithotripsy Unit, model Storz F2, serial number OR-159 to replace the existing Lithotripsy Unit, model Storz F2, serial number OR-519. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Construction and & Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation 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: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Mr. Brett
January 12, 2015
Page 2

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

Sincerely,



Bernetta Thorne-Williams,
Project Analyst



Martha J. Frisone, Assistant Chief
Certificate of Need

cc: Assistant Chief, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHR

Williams, Bernetta

From: Brett, Anthony <ABrett@wcsr.com>
Sent: Tuesday, December 23, 2014 3:03 PM
To: Frisone, Martha; Williams, Bernetta
Subject: Fayetteville Lithotripters Limited Partnership--Virginia I
Attachments: Exemption Letter and Correction Needed.pdf; Fayetteville Lithotripters Limited Partnership-Virginia I

Thank you for your response. Unfortunately, there is an understandable error in the listing of the serial number of the replacement lithotripter (see the correction marked on the third page of the Exemption Letter attachment and my letter of November 24, 2014 included in the second attachment). Please send a corrected letter at your convenience. If there are any questions, please let me know at your convenience. And do have a wonderful holidays!

Anthony H. Brett
Womble Carlyle Sandridge & Rice, LLP
One West Fourth Street, Suite 1200
Winston-Salem, NC 27101
phone: (336) 721-3620
fax: (336) 733-8331
email: abrett@wcsr.com

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

Pat McCrory
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Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

December 18, 2014

Mr. Anthony H. Brett
Womble, Carlyle, Sandridge & Rice
One West Fourth Street
Winston-Salem, NC 27101

Exempt from Review - Replacement Equipment

Facility: Fayetteville Lithotripters Limited Partnership – Virginia I
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County: Chowan, Dare and Pasquotank Counties

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Moreover, you need to contact the Construction and & Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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Mr. Brett
December 18, 2014
Page 2

Sincerely,



Bernetta Thorne-Williams,
Project Analyst



Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Construction Section, DHR
Acute and Home Care Licensure and Certification Section, DHR



One West Fourth Street
Winston-Salem, NC 27101

Telephone: (336) 721-3600
Fax: (336) 721-3660
www.wcsr.com

Received by
the CON Section
DEC 1 2014

Anthony H. Brett
Direct Dial: 336-721-3620
Direct Fax: 336-733-8331
E-mail: ABrett@wcsr.com

November 24, 2014

**Via Certified Mail, Return-Receipt Requested
Via E-mail [martha.frisone@dhhs.nc.gov]**

Martha Frisone, Interim Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
N.C. Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Request for Exemption from Review-Replace Equipment Destroyed
by Accident/Fayetteville Lithotripters Limited Partnership-Virginia I/
Replace One Mobile Lithotripsy Unit to be Used at Established Sites/
Chowan, Dare, and Pasquotank Counties

Dear Ms. Frisone:

As counsel for Fayetteville Lithotripters Limited Partnership – Virginia I (the “Partnership”), I am providing this information concerning a request for confirmation of exemption of the transaction described in this letter from certificate of need review pursuant to N.C.G.S. § 131E-184(a)(5) and/or (7). The transaction is for replacement equipment as defined in N.C.G.S. § 131E-176(22a) and 10A NCAC 14C.0303.

I have discussed this transaction with the appropriate Project Analyst for Health Service Area VI as the established sites are in the Counties of Chowan, Dare and Pasquotank. Based upon the requirements of the governing statutes and regulations and my discussions with Ms. Thorne-Williams, it is my understanding that the information contained in this letter is sufficient for the issuance of the confirmation of exemption requested. However, if there are any questions, please let me know at your earliest convenience.

The Partnership is a grandfathered mobile lithotripsy service by virtue of its operations in North Carolina beginning in 1990. As the Partnership was providing the service prior to March

November 24, 2014

18, 1993, it may provide mobile lithotripsy services throughout North Carolina. As reflected in the 2014 State Medical Facilities Plan, the Partnership's existing sites are Albemarle Health (Elizabeth City in Pasquotank County), The Outer Banks Hospital (Nags Head in Dare County), and Vidant Chowan Hospital (Edenton in Chowan County). In addition, the Partnership provides mobile lithotripsy services at various hospitals in Virginia.

The Partnership operated a Storz F-2 lithotripter, Serial Number OR-519 (the "Former Equipment"), which it acquired by purchase in November of 2013. The Partnership proposes to replace the Former Equipment with a new Storz F2 lithotripter, Serial Number OR-159 (the "Replacement Equipment"), which will be acquired by purchase and placed in operation in North Carolina no earlier than December 1, 2014.

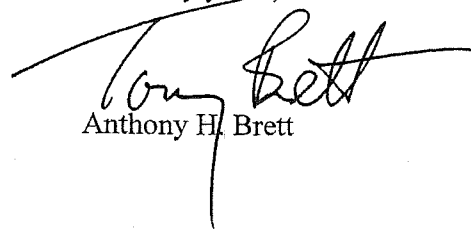
The Replacement Equipment has a cost of \$337,662 plus sales taxes (quotation attached). Therefore, the combined cost of the Replacement Equipment and all other items necessary for its operation are below \$2 million. The Former Equipment is out of service, removed from North Carolina, and will become the property of the Partnership's insurance carrier.

The reason that replacement is necessary is that the Former Equipment was damaged beyond repair when it fell off a truck platform on October 10, 2014 (see attached Transport Damage Report dated October 22, 2014). The Former Equipment was the subject of the attached Exemption Letter of November 15, 2013.

The Replacement Equipment is not capable of performing any additional procedures that are not performed by the Existing Equipment; the Replacement Equipment is the identical model lithotripter as the Former Equipment. The Replacement Equipment will not result in an increase in patient charges during its first twelve months of operation, and the Replacement Equipment will not result in an increase in per procedure operating expenses of the Partnership during the first twelve months of its operation.

Your timely consideration of this request for confirmation of exemption from certificate of need review is greatly appreciated.

Sincerely yours,



Anthony H. Brett

AHB/mib

Enclosures (Quotation, Transport Damage Report, and Exemption Letter)

cc: Bernetta Thorne-Williams (via email at bernetta.williams@dhhs.nc.gov)
Robert Grimmer, Area Vice President

QUOTATION & SALES AGREEMENT No.: 1429701.PA
OR519 REPLACEMENT

This Quotation Supersedes all Previous Quotations



Karl Storz
 Lithotripsy-America, Inc

1000 Cobb Place Blvd
 Bldg 400, Suite 450
 Kennesaw, GA 30144

Toll Free 800 965 4846
 Phone 678 354 6229
 Fax 678 354 6943

TO Healthtronics

Date: November 18, 2014

Fayetteville Lithotripters Limited Partnership - Virginia I
 9825 Spectrum Dr., Bldg. 3
 Austin, TX 78717
 ATTN: Mr. Gary Kozen, Vice President - Urology Operations

DESCRIPTION	
1 ea	<p>MODULITH SLX-F2 Lithotripter transportable Version:</p> <ul style="list-style-type: none"> - Concept: Lithotripter with integrated patient table for ESWL & Endourology - Imaging Systems: For In-line X-ray localisation and/or In-line ultrasound localisation - Table top: Hydraulic positioning in X - Y - Z direction - Longitudinal movement: 420 mm - Lateral movement: ± 70 mm - motorised height adjustment: 800 mm – 1140 mm - Table top length: 1395 mm (with table top extension 2027 mm) - Table top width: 720 mm (without side rails) - Max. patient weight: 225 kg - SLX-F2 operating panel: Control of all system functions <p>Attachment for transportable version</p> <ul style="list-style-type: none"> - In-Line X-ray localisation: Cross-Hair insert into shock wave source for p.a. and 30° X-ray projection with X-ray C-arm - Transport attachment: Integrated forklift for easy transportation within the hospital - Lithotripter Operating panel: Holder with attachment for SLX-F2 Operating panel to be installed at the rear of the lithotripter <p>PM-8000:</p> <ul style="list-style-type: none"> - ECG system: Three channel patient monitor - Function: ECG monitoring & shock wave triggering - Additional features: SpO₂, NIPB & Temperature measuring <p>MODULITH SLX-F2 Urokit-Flex for Endourology:</p> <ul style="list-style-type: none"> - Urokit items: Holder for flexible drain bag, table insert & adjustable IV pole - Disposables: 5 plastic flexible drain bags included (footswitch not included) <p>180 mm Shock Wave Source:</p> <ul style="list-style-type: none"> - Shock wave source: Cylindrical electromagnetic shock wave coil with parabolic reflector - Shock wave source diameter: 300 mm - Shock Wave penetration depth: 0 - 180 mm - Ultrasound localisation path: In-line a.p./p.a. - X-ray localisation path: In-line a.p./p.a. and 30° lateral with airbags for improved image quality <p>Single Focus Shock Wave Generator:</p> <ul style="list-style-type: none"> - Concept: Shock wave generator with wide range of energy for the entire range of ESWL - Precision Focus: <ul style="list-style-type: none"> • focus pressure: 5 - 150 MPa • focus dimensions: Ø 6 mm x 28 mm • energy flux density: 0.42 - 3.65 mJ/mm² - Energy levels: 26 steps - Trigger frequency: 60/90/120/180/240 shock-waves/min & ecg

WARRANTY		
1 ea	12-Month Warranty (Refer to Terms and Conditions of Sale, Section 8.0)	
1 ea	6-Month Extension of Warranty Period on the Table & C-Arm (Consumables not included)	
SYSTEM TOTAL		\$332,412.00
SHIPPING & HANDLING (BASED ON CUSTOMER PICKUP IN KENNESAW, GA)		\$5,250.00
TOTAL PRICE*		\$337,662.00

STORZ MEDICAL

Karl Storz Lithotripsy-America
Mr. Cory Alcala
1000 Cobb Place Blvd
Building 400, Suite 450
Kennesaw, GA 30144
USA

October 22, 2014

Transport Damage Report

To whom it may concern

We have been informed by email dated October 21 2014 of an incident during transportation of a product MODULITH SLX F2 falling off a truck platform of approx. 1.5m height. 3 attached photos show the position of the product laying on the side after the drop off the platform.

The product has been transferred to the facilities of Karl Storz Lithotripsy-America, Inc., 1000 Cobb Place Blvd., Building 400, Suite 450; Kennesaw, GA 30144.

A qualified investigation has not been performed and is not possible on the basis of the given information.

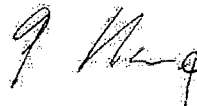
Intended use of the product is the localisation and disintegration of stones in kidney, bladder and biliary duct by means of extracorporeal application of shock waves with high precision. Coincidence of targeted area and location of shock wave application is critical.

Based on the photographs and the drop height of approx. 1.5m the following statement can be made:

- The mechanical structure has been deformed in it's entirety
- Dimensional integrity which is a critical condition for precise localisation of target area and spatial coincidence with the therapy focus have been altered by the mechanical impact.
- The product has not been designed to withstand drops from considerable levels on hard floor. Mechanical Components have been dimensioned with safety factors of 2.5 to 4 against static load. A falling level of 1.5m on hard floor induces an acceleration of 25 to 50 g. This means that the applied stress has exceeded the tested level by a factor of 6.25 to 20.
- Deviation of conditions for intended use of the product is beyond remedy and can not be established by any repair procedure or replacement of parts

With best Regards,

STORZ MEDICAL AG


Dr. Gerold Heindl
CEO



Attached:

Attachment 1
Attachment 2

Email notification dated 2014 10 21
3 Photographs

--- START --- ATTACHMENT 1 Email notification dated 2014 10 21

Von: Alcala, Cory [<mailto:Cory.Alcala@karlstorz.com>]
Gesendet: Dienstag, 21. Oktober 2014 09:33
An: Steffen Hofer | STORZ MEDICAL AG
Betreff: Fwd: FW:

OR 519

Sent from my iPhone

Begin forwarded message:

From: "Gary Kozen" <gary.kozen@healthtronics.com>
To: "Alcala, Cory" <Cory.Alcala@karlstorz.com>
Subject: FW:

FYI

Gary J. Kozen
Vice President
HealthTronics, Inc | 9825 Spectrum Dr, Bldg 3 | Austin, TX 78717
512-721-4738 office 910-489-2412 mobile 800-706-6502
gary.kozen@healthtronics.com<<mailto:gary.kozen@healthtronics.com>>

[[cid:image002.jpg@01CF36F6.7A713D10](#)]

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From: Patrick Alejos
Sent: Friday, October 10, 2014 9:49 AM
To: Gary Kozen
Subject: FW:

Patrick Alejos RN [[cid:image003.png@01CFE46F.43A17030](#)]
Senior Director of Operations
HealthTronics, Inc. 9825 Spectrum Drive, Bldg. 3, Austin, TX 78717
Office 210.682.4057 mobile 210.602.1987 fax 210.682.4726
page 3 of 6

pat.alejos@healthtronics.com<<mailto:pat.alejos@healthtronics.com>>

[cid:image002.jpg@01CE36F6.7A713D10]

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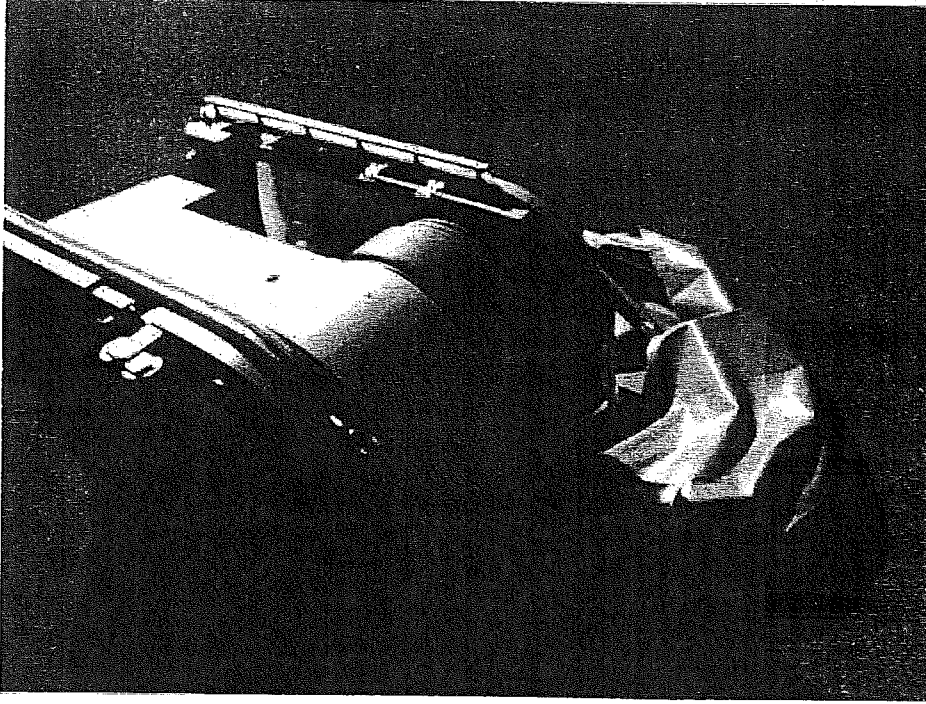
From: 2106021987@mms.att.net<<mailto:2106021987@mms.att.net>>
[<mailto:2106021987@mms.att.net>]

Sent: Friday, October 10, 2014 9:48 AM

To: Patrick Alejos

Subject:

--- END --- ATTACHMENT 1 Email notification dated 2014 10 21

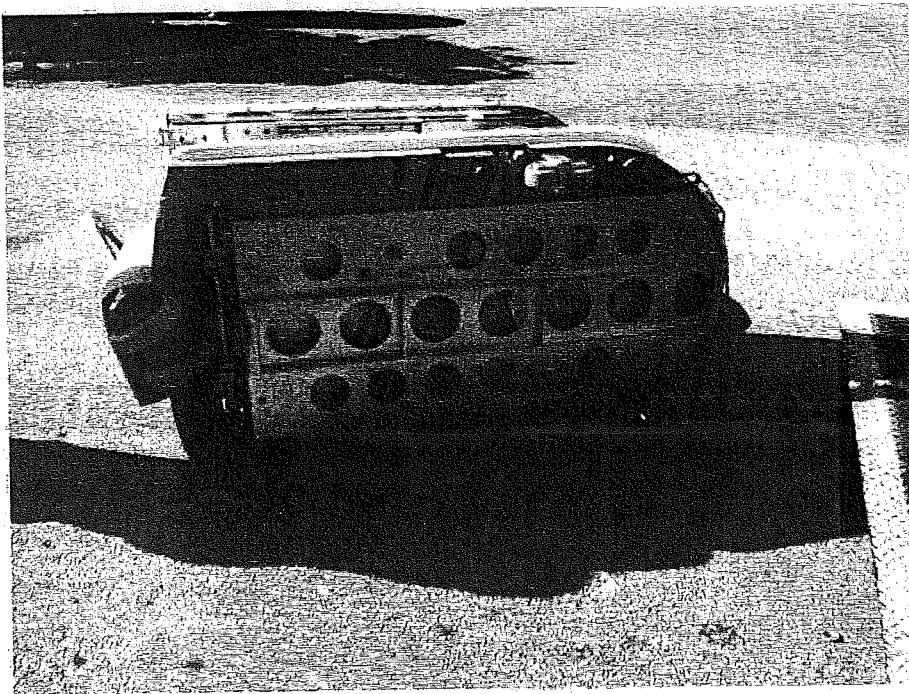
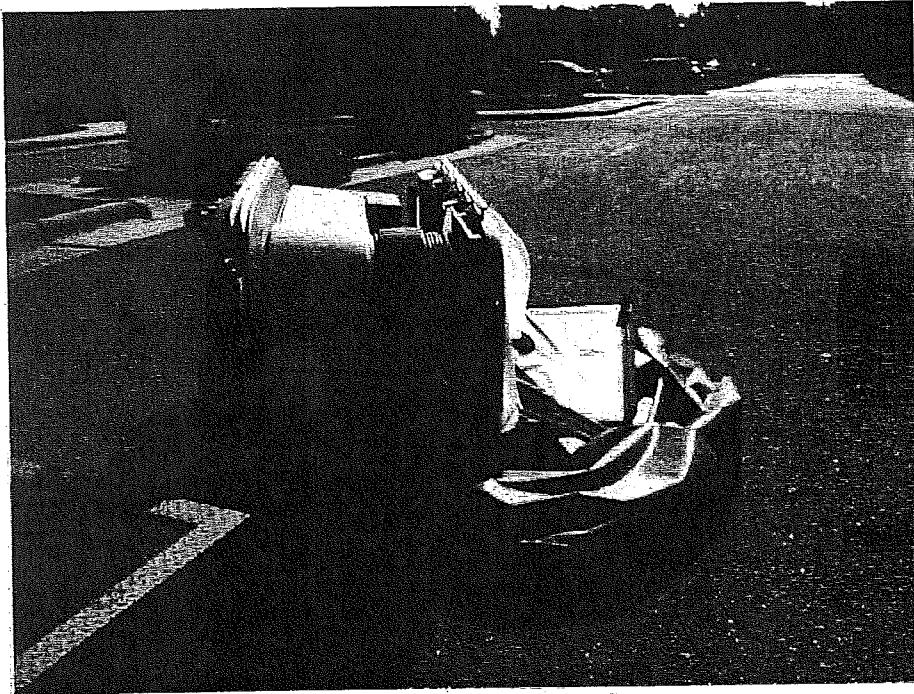


--- END --- Attachment 2

3 Photographs

--- START --- Attachment 2

3 Photographs





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

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Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

November 15, 2013

Mr. Anthony H. Brett
Womble, Carlyle, Sandridge & Rice
One West Fourth Street
Winston-Salem, NC 27101

Exempt from Review - Replacement Equipment

Facility: Fayetteville Lithotripters Limited Partnership – Virginia I
Project Description: Replacement of existing mobile Lithotripsy Unit
County: Chowan, Dare and Pasquotank Counties
FID #: Vidant Chowan 933102
Outer Banks Hospital 980550
Albemarle Health 952933

Dear Brett

In response to your letter of October 23, 2013 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Lithotripsy Unit, model Storz F2, serial number OR-519 to replace the existing Lithotripsy Unit, model Siemens, serial number 1147. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

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Telephone: 919-855-3873 • Fax: 919-733-8139

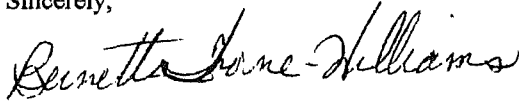
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Mr. Brett
November 15, 2013
Page 2

Sincerely,

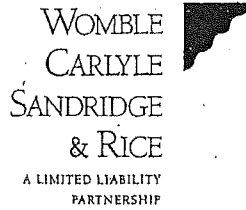


Bernetta Thorne-Williams,
Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

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



One West Fourth Street
Winston-Salem, NC 27101

Telephone: (336) 721-3600
Fax: (336) 721-3660
www.wcsr.com



*BTW
copy*

Anthony H. Brett
Direct Dial: 336-721-3620
Direct Fax: 336-733-8331
E-mail: ABrett@wcsr.com

November 24, 2014

Via Certified Mail, Return-Receipt Requested
Via E-mail [martha.frisone@dhhs.nc.gov]

Martha Frisone, Interim Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
N.C. Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Certified Article Number

7196 5008 9111 2136 8019

SENDERS RECORD

Re: Request for Exemption from Review-Replace Equipment Destroyed
by Accident/Fayetteville Lithotripters Limited Partnership-Virginia I/
Replace One Mobile Lithotripsy Unit to be Used at Established Sites/
Chowan, Dare, and Pasquotank Counties

Dear Ms. Frisone:

As counsel for Fayetteville Lithotripters Limited Partnership – Virginia I (the “Partnership”), I am providing this information concerning a request for confirmation of exemption of the transaction described in this letter from certificate of need review pursuant to N.C.G.S. § 131E-184(a)(5) and/or (7). The transaction is for replacement equipment as defined in N.C.G.S. § 131E-176(22a) and 10A NCAC 14C.0303.

I have discussed this transaction with the appropriate Project Analyst for Health Service Area VI as the established sites are in the Counties of Chowan, Dare and Pasquotank. Based upon the requirements of the governing statutes and regulations and my discussions with Ms. Thorne-Williams, it is my understanding that the information contained in this letter is sufficient for the issuance of the confirmation of exemption requested. However, if there are any questions, please let me know at your earliest convenience.

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November 24, 2014

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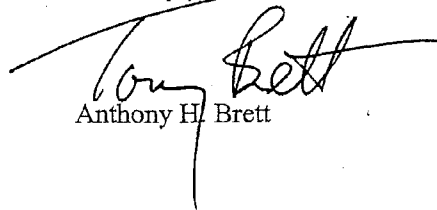
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The reason that replacement is necessary is that the Former Equipment was damaged beyond repair when it fell off a truck platform on October 10, 2014 (see attached Transport Damage Report dated October 22, 2014). The Former Equipment was the subject of the attached Exemption Letter of November 15, 2013.

The Replacement Equipment is not capable of performing any additional procedures that are not performed by the Existing Equipment; the Replacement Equipment is the identical model lithotripter as the Former Equipment. The Replacement Equipment will not result in an increase in patient charges during its first twelve months of operation, and the Replacement Equipment will not result in an increase in per procedure operating expenses of the Partnership during the first twelve months of its operation.

Your timely consideration of this request for confirmation of exemption from certificate of need review is greatly appreciated.

Sincerely yours,



Anthony H. Brett

AHB/mib

Enclosures (Quotation, Transport Damage Report, and Exemption Letter)

cc: Bernetta Thorne-Williams (via email at bernetta.williams@dhhs.nc.gov)
Robert Grimmer, Area Vice President

STORZ MEDICAL

Karl Storz Lithotripsy-America
Mr. Cory Alcala
1000 Cobb Place Blvd
Building 400, Suite 450
Kennesaw, GA 30144
USA

October 22, 2014

Transport Damage Report

To whom it may concern

We have been informed by email dated October 21 2014 of an incident during transportation of a product MODULITH SLX F2 falling off a truck platform of approx. 1.5m height. 3 attached photos show the position of the product laying on the side after the drop off the platform.

The product has been transferred to the facilities of Karl Storz Lithotripsy-America, Inc., 1000 Cobb Place Blvd., Building 400, Suite 450, Kennesaw, GA 30144.

A qualified investigation has not been performed and is not possible on the basis of the given information.

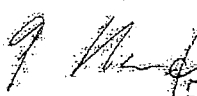
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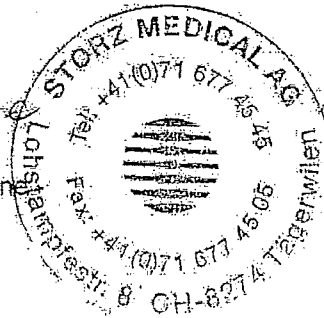
Based on the photographs and the drop height of approx. 1.5m the following statement can be made:

- The mechanical structure has been deformed in it's entirety
- Dimensional integrity which is a critical condition for precise localisation of target area and spatial coincidence with the therapy focus have been altered by the mechanical impact.
- The product has not been designed to withstand drops from considerable levels on hard floor. Mechanical Components have been dimensioned with safety factors of 2.5 to 4 against static load. A falling level of 1.5m on hard floor induces an acceleration of 25 to 50 g. This means that the applied stress has exceeded the tested level by a factor of 6.25 to 20.
- Deviation of conditions for intended use of the product is beyond remedy and can not be established by any repair procedure or replacement of parts

With best Regards,

STORZ MEDICAL AG


Dr. Gerold Heine
CEO



Attached:

Attachment 1

Attachment 2

Email notification dated 2014 10 21

3 Photographs

--- START --- ATTACHMENT 1 Email notification dated 2014 10 21

Von: Alcala, Cory [<mailto:Cory.Alcala@karlstorz.com>]
Gesendet: Dienstag, 21. Oktober 2014 09:33
An: Steffen Hofer | STORZ MEDICAL AG
Betreff: Fwd: FW:

OR 519

Sent from my iPhone

Begin forwarded message:

From: "Gary Kozen" <gary.kozen@healthtronics.com>
To: "Alcala, Cory" <Cory.Alcala@karlstorz.com>
Subject: FW:

FYI

Gary J. Kozen
Vice President
HealthTronics, Inc | 9825 Spectrum Dr, Bldg 3 | Austin, TX 78717
512-721-4738 office 910-489-2412 mobile 800-706-6502
gary.kozen@healthtronics.com <<mailto:gary.kozen@healthtronics.com>>

[[cid:image002.jpg@01CF36F6.7A713D10](#)]

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From: Patrick Alejos
Sent: Friday, October 10, 2014 9:49 AM
To: Gary Kozen
Subject: FW:

Patrick Alejos RN [[cid:image003.png@01CFE46F.43A17030](#)]
Senior Director of Operations
HealthTronics, Inc. 9825 Spectrum Drive, Bldg. 3, Austin, TX 78717
Office 210.682.4057 mobile 210.602.1987 fax 210.682.4726

page 3 of 6

pat.alejos@healthtronics.com <<mailto:pat.alejos@healthtronics.com>>

[cid:image002.jpg@01CE36F6.7A713D10]

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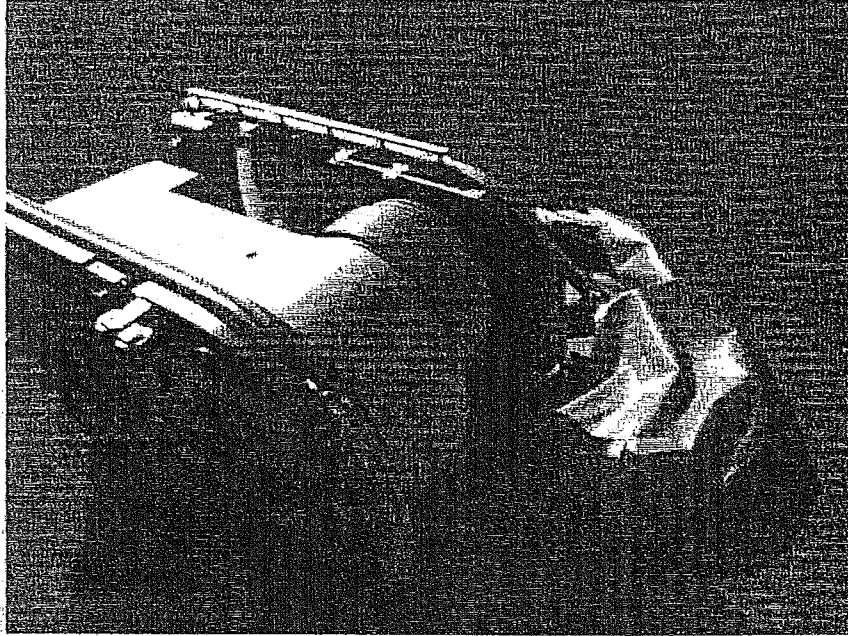
From: 2106021987@mms.att.net <<mailto:2106021987@mms.att.net>>
[<mailto:2106021987@mms.att.net>]

Sent: Friday, October 10, 2014 9:48 AM

To: Patrick Alejos

Subject:

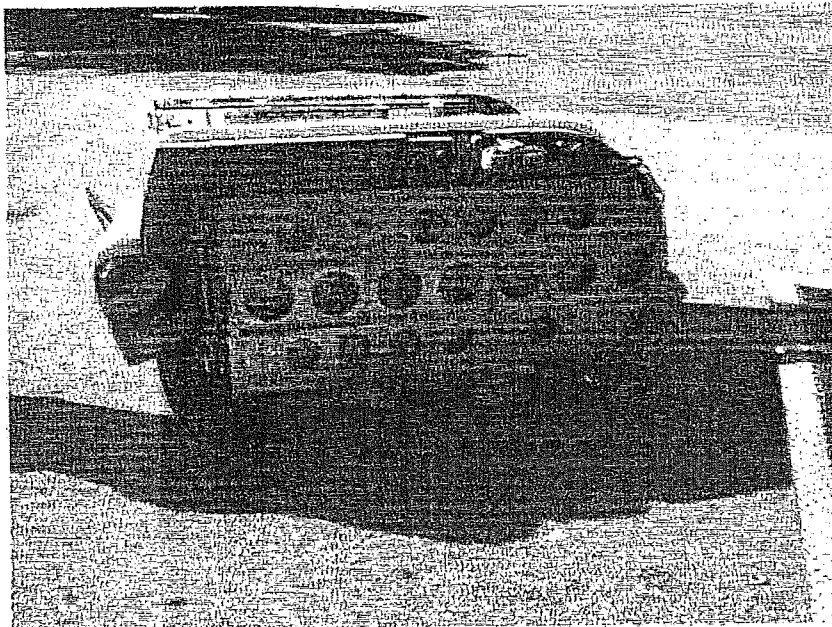
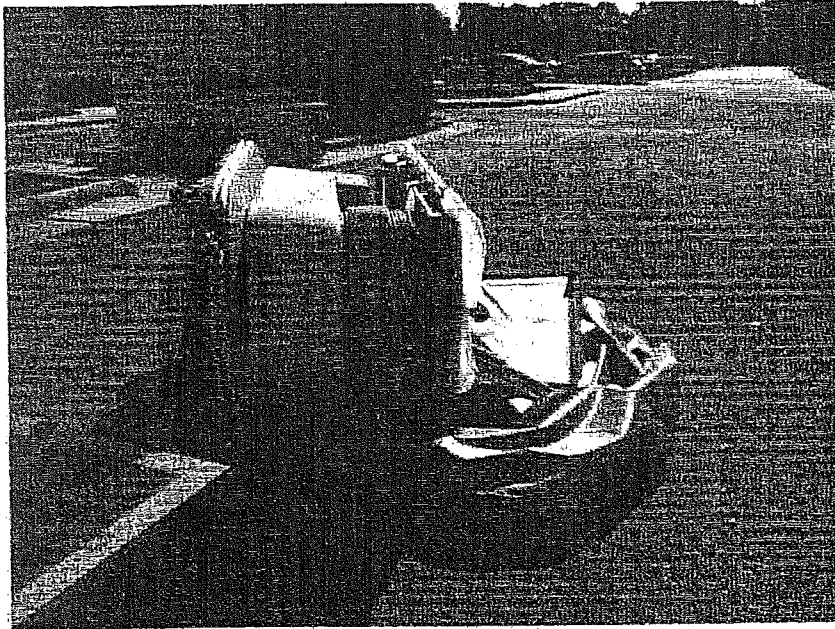
--- END --- ATTACHMENT 1 Email notification dated 2014 10 21



--- END --- Attachment 2 . 3 Photographs

--- START --- Attachment 2

3 Photographs



QUOTATION & SALES AGREEMENT No.: 1429701.PA

OR519 REPLACEMENT

This Quotation Supersedes all Previous Quotations



Karl Storz
Lithotripsy-America, Inc

1000 Cobb Place Blvd
Bldg 400, Suite 450
Kennesaw, GA 30144

Toll Free 800 965 4846
Phone 678 354 6229
Fax 678 354 6943

TO HealthTronics

Date: November 18, 2014

Fayetteville Lithotripters Limited Partnership - Virginia I
9825 Spectrum Dr., Bldg. 3
Austin, TX 78717
ATTN: Mr. Gary Kozen, Vice President - Urology Operations

DESCRIPTION	
1 ea	<p>MODULITH SLX-F2 Lithotripter transportable Version:</p> <ul style="list-style-type: none"> - Concept: Lithotripter with integrated patient table for ESWL & Endourology - Imaging Systems: For In-line X-ray localisation and/or In-line ultrasound localisation - Table top: Hydraulic positioning in X - Y - Z direction - Longitudinal movement: 420 mm - Lateral movement: ± 70 mm - motorised height adjustment: 800 mm – 1140 mm - Table top length: 1395 mm (with table top extension 2027 mm) - Table top width: 720 mm (without side rails) - Max. patient weight: 225 kg - SLX-F2 operating panel: Control of all system functions <p>Attachment for transportable version</p> <ul style="list-style-type: none"> - In-Line X-ray localisation: Cross-Hair insert into shock wave source for p.a. and 30° X-ray projection with X-ray C-arm - Transport attachment: Integrated forklift for easy transportation within the hospital - Lithotripter Operating panel: Holder with attachment for SLX-F2 Operating panel to be installed at the rear of the lithotripter <p>PM-8000:</p> <ul style="list-style-type: none"> - ECG system: Three channel patient monitor - Function: ECG monitoring & shock wave triggering - Additional features: SpO₂, NIPB & Temperature measuring <p>MODULITH SLX-F2 Urokit-Flex for Endourology:</p> <ul style="list-style-type: none"> - Urokit items: Holder for flexible drain bag, table insert & adjustable IV pole - Disposables: 5 plastic flexible drain bags included (footswitch not included) <p>180 mm Shock Wave Source:</p> <ul style="list-style-type: none"> - Shock wave source: Cylindrical electromagnetic shock wave coil with parabolic reflector - Shock wave source diameter: 300 mm - Shock Wave penetration depth: 0 – 180 mm - Ultrasound localisation path: in-line a.p./p.a. - X-ray localisation path: In-line a.p./p.a. and 30° lateral with airbags for improved image quality <p>Single Focus Shock Wave Generator:</p> <ul style="list-style-type: none"> - Concept: Shock wave generator with wide range of energy for the entire range of ESWL - Precision Focus: <ul style="list-style-type: none"> • focus pressure: 5 – 150 MPa • focus dimensions: Ø 6 mm x 28 mm • energy flux density: 0.42 – 3.65 mJ/mm² - Energy levels: 26 steps - Trigger frequency: 60/90/120/180/240 shock-waves/min & ecg

WARRANTY		
1 ea	12-Month Warranty (Refer to Terms and Conditions of Sale, Section 8.0)	
1 ea	6-Month Extension of Warranty Period on the Table & C-Arm (Consumables not included)	
SYSTEM TOTAL		\$332,412.00
SHIPPING & HANDLING (BASED ON CUSTOMER PICKUP IN KENNESAW, GA)		\$5,250.00
TOTAL PRICE*		\$337,662.00



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

November 15, 2013

Mr. Anthony H. Brett
Womble, Carlyle, Sandridge & Rice
One West Fourth Street
Winston-Salem, NC 27101

Exempt from Review - Replacement Equipment

Facility:	Fayetteville Lithotripters Limited Partnership – Virginia I		
Project Description:	Replacement of existing mobile Lithotripsy Unit		
County:	Chowan, Dare and Pasquotank Counties		
FID #:	Vidant Chowan	933102	
	Outer Banks Hospital	980550	
	Albemarle Health	952933	

Dear Brett

In response to your letter of October 23, 2013 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Lithotripsy Unit, model Storz F2, serial number OR-519 to replace the existing Lithotripsy Unit, model Siemens, serial number 1147. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Construction and Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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

Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

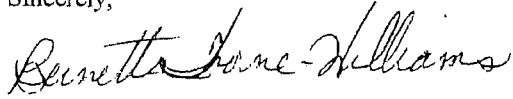
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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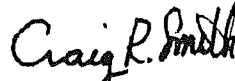


Mr. Brett
November 15, 2013
Page 2

Sincerely,



Bernetta Thorne-Williams,
Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

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

Frisone, Martha

From: Brett, Anthony <ABrett@wcsr.com>
Sent: Tuesday, December 23, 2014 3:03 PM
To: Frisone, Martha; Williams, Bernetta
Subject: Fayetteville Lithotripters Limited Partnership--Virginia I
Attachments: Exemption Letter and Correction Needed.pdf; Fayetteville Lithotripters Limited Partnership-Virginia I

Thank you for your response. Unfortunately, there is an understandable error in the listing of the serial number of the replacement lithotripter (see the correction marked on the third page of the Exemption Letter attachment and my letter of November 24, 2014 included in the second attachment). Please send a corrected letter at your convenience. If there are any questions, please let me know at your convenience. And do have a wonderful holidays!

Anthony H. Brett
Womble Carlyle Sandridge & Rice, LLP
One West Fourth Street, Suite 1200
Winston-Salem, NC 27101
phone: (336) 721-3620
fax: (336) 733-8331
email: abrett@wcsr.com

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*See the attachment.
Please prepare a corrected letter.
Thanks
M*



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

December 18, 2014

Mr. Anthony H. Brett
Womble, Carlyle, Sandridge & Rice
One West Fourth Street
Winston-Salem, NC 27101

Exempt from Review - Replacement Equipment

Facility: Fayetteville Lithotripters Limited Partnership – Virginia I
Project Description: Replace existing mobile lithotripsy unit
County: Chowan, Dare and Pasquotank Counties

Dear Mr. Brett:

In response to your letter of November 24, 2014 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Lithotripsy Unit, model Storz F2, serial number OR-~~519~~ to replace the existing Lithotripsy Unit, model Storz F2, serial number OR-519.

159 ↓ This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

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Certificate of Need Section

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