

# 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

August 20, 2021

James Rouse James.rouse@emergeortho.com Anna.Weaver@brunswicksurgerycenter.com

No Review	
Record #:	3461
Date of Request:	August 10, 2021
Facility Name:	Brunswick Surgery Center
FID #:	160564
<b>Business Name:</b>	Brunswick Surgery Center, LLC
Business #:	2509
Project Description:	Acquire a Zimmer Biomet Rosa robotic knee surgical system
County:	Brunswick

Dear Mr. Rouse:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Danze MSapout

Tanya M. Saporito

Micheala Mitra 10

Micheala Mitchell Chief

cc: Acute and Home Care Licensure and Certification 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



August 10, 2021

Ms. Micheala Mitchell Chief, Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603

RE: Request for No Review Determination for Acquisition of Surgical Equipment at Brunswick Surgery Center/Brunswick County

Dear Ms. Mitchell:

Brunswick Surgery Center, LLC (BSC), intends to acquire and operate a surgical robotic system, to assist in minimally invasive orthopedic surgical procedures at its licensed ambulatory surgical facility (ASF) that currently exists at 1168 East Cutlar Crossing, Suite 101 in Leland. BSC requests a determination that acquisition and operation of this equipment at this location does not constitute acquisition of "major medical equipment" pursuant to NCGS 131E-176(14)(o), and thus does not represent development of a "new institutional health services" and will not otherwise be subject to certificate of need (CON) review.

BSC plans to acquire a new Zimmer Biomet Rosa robotic knee surgical system to assist surgeons in performing Total Knee Arthroscopy (TKA). The purchase price for the Rosa system is \$624,000 (see Attachment). Including the applicable 6.75% Brunswick County sales tax rate, the total acquisition cost of the robotic surgical equipment is \$666,120 (\$624,000 + \$42,120).

No renovations or upfit of the ASF are required in order to accommodate this equipment and make it operational, and there are no other costs that BSC must incur to acquire the Zimmer Biomet equipment and make it operational.

NCGS 131E-176(14)(o) states "Major medical equipment". - A single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment.

1168 East Cutlar Crossing Suite 101 Leland, NC 28451

BrunswickSurgeryCenter.com

TEL: 910.660.4600 Fax: 910.660.4519



Based on the information provided in this letter, BSC requests written confirmation from the Division of Health Service Regulation that this planned acquisition of the Zimmer Biomet Rosa surgical robotic equipment does not require CON review, because the acquisition does not meet the definition of "major medical equipment" as specified in NCGS 131E-176(14)(o), and it does not constitute any other type of "new institutional health service" requiring a CON, as that term is defined in NCGS 131E-176(16).

I appreciate your attention to this matter. Please contact me at 910.332.1521 extension 31228 or <u>james.rouse@emergeortho.com</u> regarding any questions concerning this request.

Sincerely,

new yr

Anna Weaver, MSN. RN, CNOR Administrator Brunswick Surgery Center, LLC

Attachment: Vendor Equipment Quotation

1168 East Cutlar Crossing Suite 101 Leland, NC 28451

TEL: 910.660.4600 Fax: 910.660.4519

BrunswickSurgeryCenter.com

Zimmer Biomet 6001 E Royalton Road, Ste #100 Broadview Heights OH 44147



Brunswick Surgery Center, LLC

2716 ASHTON DRIVE

WILMINGTON, NC 28412

ZB Account # 116792

Dear Valued Customer,

Thank you for choosing Zimmer Biomet for your capital equipment needs. Included in this packet, you will find the following documents:

#### ROSA<sup>®</sup> iD Agreement

Please complete all of the above documentation and return an executed copy to capitalsolutions@zimmerbiomet.com.

Additionally, with the return of the documentation, please also complete the fields below with a contact person for compliance statements, so we are able to maintain communication on your contractual performance throughout the term.

Compliance Contact Name: _	ANNA M WEAVER
Contact Title / Department:	
Contact email address: and	a. weaver@brunswicksurgerycenter.com
Contact phone number:	252 714 3303

If there are any questions, please feel free to contact your local Zimmer Sales Representative, or send an email to <u>capitalsolutions@zimmerbiomet.com</u>.

Sincerely,

Zimmer Biomet Connect Capital Solutions Team

#### **ROSA® ID AGREEMENT**

#### Brunswick Surgery Center, LLC 2716 ASHTON DRIVE WILMINGTON, NC 28412 ("Customer")

This ROSA<sup>©</sup> iD Agreement (the "iD Agreement") is between Customer and Zimmer US, Inc., together with its affiliates ("ZB"), and Brunswick Surgery Center, LLC ("Customer"). Each ZB and Customer is referred to herein as a "Party" and collectively or together as the "Parties."

Customer may earn a Rebate (defined below) Customer's purchase on all Zimmer US, Inc. knee and hip products between the Parties ("Products"). The Rebate shall be directed and applied to the placement and use of the equipment set forth in Section A ("Equipment") for a period of sixty (60) months ("Term").

#### Section A: Equipment

Part #	Product Description	Quantity
02-8020-100-01	ROSA® KNEE PLATFORM US PL B	1
MANUFWARRK1	PREMIUM WARRANTY ROSA KNEE YEARS 1	1
20-8085-020-00	X-PSI Calibration Kit	1
KT-8020-060-00	PERSONA IMPLANT KIT	2

1. The Term shall commence on the first day of the month following installation of the Equipment and will continue for the Term specified above.

2. Customer shall receive a rebate of 18.00% against the purchase price of Products purchased in excess of the Minimum Purchase Commitment (defined below) during the Term ("Rebate") and Customer hereby directs Rebate to be applied towards the Payment. ZB will evaluate Customer's annual usage and shall invoice Customer for the Payment less any Rebate for any annual period in which Customer does not meet the Minimum Purchase Commitment. Total Rebate shall not exceed the Payment. Any Rebate earned in the annual period beyond what is required to meet the Payment will be credited toward the Payment for the next succeeding annual period. All invoices shall become due and payable within 30 days of the invoice date.

3. Customer shall owe \$90,540.00 for the first twelve (12) months of the Term, and \$133,365.00 annually thereafter for the remainder of the Term ("Payment") to ZB in exchange for ZB's placement of Equipment for Customer's use during the Term. Customer also commits to purchase Products totaling at least \$33,120.00 annually (the "Minimum Purchase Commitment") from ZB during the Term. ZB shall invoice Customer for Products as they are ordered and shall issue annual compliance statements to Customer to track purchases against the Minimum Purchase Commitment.

4. In accordance with the discount safe harbor to the federal anti-kickback statute (42 C.F.R. § 1001.952(h)), Customer agrees to fully and accurately report all amounts paid and Rebate earned hereunder to Medicare, Medicaid and all other federal and state health care programs and third-party payors as required by applicable law or agreement and to provide copies of this iD Agreement and all other applicable documentation and invoices to representatives of these programs and third-party payors upon their request.

5. Title to the Equipment shall remain with ZB at all times during the Term of the iD Agreement. Customer shall not encumber the Equipment in any way, and further shall not remove the Equipment from Customer's place of business without first obtaining written consent of ZB. Notwithstanding the foregoing, Customer hereby grants to ZB a security interest in the Equipment as security for all Customer's liabilities and obligations hereunder.

6. The following events shall constitute a default under this iD Agreement ("Event of Default"): (a) Customer violates any of the provisions under this iD Agreement; (b) Customer fails to make any payment within thirty (30) days of its due date; or (c) if any of the following actions or proceedings are not dismissed within sixty (60) days after commencement: (i) Customer's dissolution, insolvency, becoming the subject of a petition in bankruptcy or involved in any other proceeding under federal bankruptcy laws; (ii) Customer makes an assignment for benefit of creditors; or (iii) Customer is named in a suit for the appointment of a receiver. Following an Event of Default, ZB may exercise concurrently or separately, without notice to Customer, any of the following remedies: (a) repossess the Equipment; (b) terminate the iD Agreement; and (c) declare the Balance Remaining immediately due and payable. "Balance Remaining" is defined as any and all amounts due and payable but not yet paid, plus fair market value of Equipment, less any recoveries due to repossession, if applicable. Customer agrees to pay all of ZB's costs of enforcing ZB's rights against Customer, including attorneys' fees and court costs.

7. Customer agrees to accept, take delivery of, store, and maintain the Equipment in good repair, condition and in proper working order, use said Equipment as medically indicated and agrees to take full legal and financial responsibility for any and all loss, damage, or destruction of said Equipment while in Customer's possession until the Equipment is returned to ZB.

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(Z) ZIMMER BIOMET

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8. Provided Customer is not in breach of this iD Agreement, Customer shall be entitled to all Equipment warranties offered by ZB. Customer's sole remedy for breach of any Equipment warranty shall be against ZB.

9. Customer agrees that it shall (a) furnish proper storage and security for all Equipment supplied hereunder; (b) pay for all damages to the Equipment (ordinary wear and tear excepted); and (c) pay all costs of collection for unpaid amounts due to ZB, including interest at the highest rate allowed by law and attorneys' fees.

10. Customer hereby agrees to permit ZB, or its authorized representative, from time to time during normal business hours, to enter the premises where Equipment supplied hereunder is stored for the purpose of inspecting and inventorying such Equipment and/or removing such Equipment if Customer fails to meet its obligations under this iD Agreement.

11. At the end of the Term of this iD Agreement, Customer will elect to either (a) purchase all, but not less than all, of the Equipment at fair market value not to exceed \$156,000.00; (b) return the Equipment to ZB by making it available for pick-up within forty-eight (48) hours of termination and shall pay all assessable fees for loss, theft or damage as outlined in this iD Agreement; or (c) execute an extension or alternative acquisition solution under mutually agreeable terms to be agreed no less than thirty (30) days prior to end of Term.

12. During the Term or any extension to this iD Agreement, Customer will self-insure for or maintain adequate commercial general liability insurance and "all risk" property insurance covering the Equipment against physical damage or loss, including theft, for its full replacement cost. If requested by ZB, Customer shall provide evidence of such insurance coverage.

13. Customer shall not consolidate or merge with or into any other entity, liquidate, sell or dispose of all or any substantial portion of its ownership interests, properties or assets other than in the ordinary course of its business, without providing written notice to ZB. CUSTOMER HAS NO RIGHT TO SELL, TRANSFER, ASSIGN OR SUBLET THE EQUIPMENT OR THIS AGREEMENT.

14. The obligations of either Party to perform under this iD Agreement shall be excused if a Party's failure to perform or delay in performance of its obligations or responsibilities under this agreement is caused by matters beyond the claiming Party's control, which shall include, but not be limited to, acts of God, strikes or lockouts, embargo, national emergency, fire, flood, natural disaster, pandemic, civil commotion, riots, wars, revolution, acts of terrorism, blockade or acts of government preventing performance, including executive orders limiting travel and/or requiring business closure or limitations (a "Force Majeure Event"). Upon a Force Majeure Event, the claiming Party shall notify the other Party in writing of the delay. Upon the occurrence of such an event, the duties and obligations of the Parties shall be suspended without liability for the duration of the Force Majeure Event; provided, however, that if such suspension shall continue in excess of ninety (90) days, the Parties shall attempt to arrive at a mutually acceptable compromise. If the Parties are unable to reach a compromise, then this iD Agreement may be immediately terminated upon written notice by the non-affected Party.

15. THIS AGREEMENT WILL BE GOVERNED BY, ENFORCED IN AND INTERPRETED ACCORDING TO THE LAWS OF THE STATE OF DELAWARE. CUSTOMER CONSENTS TO EXCLUSIVE JURISDICTION IN THE STATE OR FEDERAL COURTS OF DELAWARE. CUSTOMER EXPRESSLY WAIVES ANY RIGHT TO A TRIAL BY JURY. In any enforcement of the terms of this iD Agreement, the prevailing party shall be entitled to recover from the non-prevailing party its reasonable attorneys' fees and costs.

16. This iD Agreement contains the entire agreement of the Parties. If any of the provisions of this iD Agreement shall be held invalid, illegal or unenforceable, that provision shall be considered inapplicable and omitted, but shall not invalidate any of the remaining provisions. No waiver or modification by either Party of any of the terms or conditions hereof shall be effective unless in writing signed by the Parties. No waiver or indulgence by ZB of any default or deviation by Customer of any required performance shall be a waiver of ZB's right to subsequent or other full and timely performance. This iD Agreement shall be binding on the Parties and their respective successors and assigns. All notices to be provided hereunder shall be mailed or delivered by email transmission or overnight courier to the respective Parties at the addresses shown herein or such other address as a Party may provide in writing from time to time.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties have executed this iD Agreement on the date of the last signature of the Parties.

Brunsw Center, LLC CIAR 0 Authorized Signature 11 (077 INNM Printed Name

2021

ESIDEUT

Jo

Title

2

Date

Zimmersus elng. Todd Tonsing

Tonsing orized Signature

Todd 6 706 84 20 974 A80876 A9F36F27D27FA

I approve this document

11:59:28 EDT

29-Jul-2021

Printed Name

Director, Capital Solutions

Title

29-Jul-2021 | 11:59:31 EDT

Date

#### **Certificate Of Completion**

Envelope Id: 667BCA618CB548BBA96798D0D04E0E2F Status: Completed Subject: Please DocuSign: 2021.07.29 (Customer Signed) (116792) Brunswick Surgery Center LLC - ROSA iD.pdf Source Envelope:

Signatures: 1 **Document Pages: 4** Initials: 0 Certificate Pages: 4 AutoNav: Enabled Envelopeld Stamping: Enabled Time Zone: (UTC-05:00) Eastern Time (US & Canada)

#### **Record Tracking**

Status: Original 7/29/2021 11:47:13 AM

#### Signer Events

**Todd Tonsing** Todd.Tonsing@zimmerbiomet.com **Director, Capital Solutions** Zimmer Biomet Security Level: Email, Account Authentication (Required)

Accepted: 9/27/2019 4:14:58 PM

Holder: Abby Kneisel Abby.Kneisel@zimmerbiomet.com

#### Signature

todd tonsing

Signature Adoption: Pre-selected Style Signature ID: 667038A2-D997-4A80-876A-9F36F27D27FA Using IP Address: 174.207.96.132 Signed using mobile With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document

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Carbon Copy Events	Status	Timestamp		
Witness Events	Signature	Timestamp		
Notary Events	Signature	Timestamp		
Envelope Summary Events	Status	Timestamps		
Envelope Sent	Hashed/Encrypted	7/29/2021 11:48:22 AM		
Certified Delivered	Security Checked	7/29/2021 11:59:08 AM		
Signing Complete	Security Checked	7/29/2021 11:59:31 AM		
Completed	Security Checked	7/29/2021 11:59:31 AM		
Payment Events	Status	Timestamps		
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## Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

### Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

### Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

### All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

## How to contact ZB CFR Part 11 Compliant:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows: To contact us by email send messages to: gowri.sekar@zimmerbiomet.com

# To advise ZB CFR Part 11 Compliant of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at gowri.sekar@zimmerbiomet.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

### To request paper copies from ZB CFR Part 11 Compliant

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to gowri.sekar@zimmerbiomet.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

### To withdraw your consent with ZB CFR Part 11 Compliant

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to gowri.sekar@zimmerbiomet.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process.

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#### Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify ZB CFR Part 11 Compliant as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by ZB CFR Part 11 Compliant during the course of your relationship with ZB CFR Part 11 Compliant.

From:	Tanya, Saporito
To:	Waller, Martha K
Subject:	FW: [External] Letter of No-review Brunswick Surgery Center LLC
Date:	Monday, August 16, 2021 10:43:05 AM
Attachments:	Zimmer ROSA ID Agreement Executed 2021 07 29.pdf 20210810141238123.pdf

It looks like the second attachment ("20211081014.....") is the one that was in the first email ......

#### Tanya Saporito, J.D.

Project Analyst <u>Division of Health Service Regulation</u>, Certificate of Need <u>NC Department of Health and Human Services</u>



Help protect your family and neighbors from COVID-19. <u>Know the 3 Ws. Wear. Wait. Wash.</u> #StayStrongNC and get the latest at <u>nc.gov/covid19</u>

Office: 919-855-3873 Tanya.saporito@dhhs.nc.gov

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

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From: Anna Weaver <Anna.Weaver@brunswicksurgerycenter.com>
Sent: Tuesday, August 10, 2021 4:41 PM
To: Tanya, Saporito <tanya.saporito@dhhs.nc.gov>
Subject: [External] Letter of No-review Brunswick Surgery Center LLC

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to <u>Report Spam.</u>

Please see attached. Thank you Anna Weaver

Anna Weaver | ASC Administrator Brunswick Surgery Center 1168 East Cutlar Crossing, Leland, NC 28451 Phone: +1 (910) 660-4600 Anna.Weaver@brunswicksurgerycenter.com | www.BrunswickSurgeryCenter.com



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