



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 #: 3642
Date of Request: August 11, 2021
Facility Name: Brunswick Surgery Center
FID #: 160564
Business Name: Brunswick Surgery Center, LLC
Business #: 2509
Project Description: Acquire a Stryker Mako robotic interactive orthopedic arm
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,

Tanya M. Saporito

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



August 11, 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 "new institutional health services" and will not otherwise be subject to certificate of need (CON) review.

BSC plans to acquire a new Stryker Mako robotic arm interactive orthopedic (RIO) system to assist surgeons in performing Total Knee Arthroscopy (TKA). The purchase price for the Mako RIO system is \$700,000 (see Attachment). Including the applicable 6.75% Brunswick County sales tax rate, the total acquisition cost of the robotic surgical equipment (including delivery and installation) is \$747,250 (\$700,000 + \$47,250).

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 Stryker Mako equipment and make it operational.

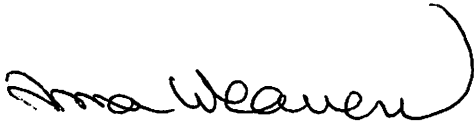
NCGS 131E-176(14)(o) states "Major medical equipment". - *A single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical 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.

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 Stryker Mako 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 or anna.weaver@brunswickurgerycenter.com regarding any questions concerning this request.

Sincerely,

A handwritten signature in black ink that reads "Anna Weaver". The signature is written in a cursive style with a large, sweeping flourish at the end.

Anna Weaver
Administrator
Brunswick Surgery Center

Attachment: Vendor Equipment Quotation

EQUIPMENT PURCHASE AGREEMENT

This Equipment Purchase Agreement, consisting of this cover page and any applicable schedules selected below (this "**Agreement**"), is entered into by and between MAKO Surgical Corp., a wholly-owned subsidiary of Stryker Corporation (MAKO Surgical Corp., or any of its affiliates, together or separately, are referred to as "**Stryker Mako**") and the undersigned healthcare provider ("**Customer**") and sets forth the terms and conditions upon which Customer will gain access to Stryker Mako's RIO® Robotic Arm Interactive Orthopedic system (the "**Equipment**") from Stryker Mako. Stryker Mako and Customer are referred to individually as a "**Party**" and collectively as the "**Parties.**"

Applicable Schedules:	<input checked="" type="checkbox"/> Schedule A – Equipment and Pricing <input checked="" type="checkbox"/> Schedule B – General Terms and Conditions <input checked="" type="checkbox"/> Schedule C – Software License Terms <input checked="" type="checkbox"/> Schedule D – Warranty and Service Terms
Effective Date and Term:	The term of this Agreement shall commence on the date this Agreement is executed by both Parties (the " Effective Date ") and shall continue until terminated by mutual written agreement of the Parties, provided Customer executed this Agreement and accepts installation of the Equipment on or prior to July 31, 2021 . Stryker Mako may, in its sole discretion, elect to install the Equipment following such date.
Equipment Installation Location:	Customer Facility: Brunswick Surgery Center, LLC 1168 East Cutlar Crossing #101, Leland, NC 28451
Stryker Mako Account Executive:	Jon Gibson

Signatures: By executing this Agreement, each signatory represents and warrants that such person is duly authorized to execute this Agreement on behalf of the respective Party.

BRUNSWICK SURGERY CENTER, LLC	MAKO SURGICAL CORP.
Signature: <u><i>Anna Weaver</i></u>	Signature: <u><i>Rick McDowell</i></u>
Name: <u>Anna Weaver</u>	Name: <u>Rick McDowell</u>
Title: <u>Administrator</u>	Title: <u>Area Sales Director</u>
Date: <u>8/11/21</u>	Date: <u>12-Aug-2021</u>
Address: <u>1168 East Cutlar Crossing #101, Leland, NC 28451</u>	Address: <u>2555 Davie Road Fort Lauderdale, FL 33317 Phone: 954-927-2044 Fax: 954-927-0446</u>

Electronically signed by: Rick McDowell Reason: I approve this document Date: Aug 12, 2021 14:33 EDT

Notices will be sent to the Parties at the addresses listed herein.

**SCHEDULE A
EQUIPMENT AND PRICING**

Mako™ System with Total Knee Application				
QTY.	PART #	EQUIPMENT	List Price	Discounted Price
1	220000	Stryker Robotic Arm System (Mako™/RIO®)		
		Includes:		
1	219999	RIO® Surgical Arm		
1	207110	RIO® Guidance Module		
1	209927	RIO® Camera Stand Assembly		
1	211394	RIO® Accessory Kit		
1	700001431977	Mako User Guides		
3	151250	Mako Power Tray		
1	200681	MAKOplasty® CT Scan Kit		
1	212183	Mako™ Total Knee Application		
		Includes:		
1	212184	Mako™ Total Knee Software License		
3	151200	Mako Array Tray		
3	110570	IMP DeMayo Leg Positioner - 25" Kit		
3	210191	Hohmann Retractor		
3	210192	Smiley Retractor		
1	212249	Surgeon & Surgical Staff Training, Total Knee		
1	214930	Mako TKA User Manuals (Master CD) M3		
TOTAL			\$ 1,015,000	\$ 700,000

CUSTOMER ACKNOWLEDGES:

Customer elects to PURCHASE the Equipment from Stryker Mako by (i) paying to Stryker Mako the discounted price as set forth in Schedule A or (ii) entering into a lease or rental agreement with a financing company for purchase of the Equipment at the price set forth in Schedule A. In either case, full payment of the discounted price shall be due to Stryker Mako NET 30 days from date of applicable invoice and Customer shall be responsible for ensuring full payment is made to Stryker Mako.

The Parties hereby agree that the Equipment Purchase Agreement dated July 29, 2021 shall terminate immediately following the Effective Date of this Agreement.

**SCHEDULE B
GENERAL TERMS AND CONDITIONS**

1. Pricing and Payment Terms: Taxes.

- 1.1. Customer agrees to gain access to the Equipment as indicated in Schedule A of this Agreement.
- 1.2. Customer acknowledges that Customer shall be responsible for payment of all applicable state, and local taxes in connection with gaining access to the Equipment, and any other payments made to Stryker Mako hereunder. Stryker Mako shall include the applicable tax in its invoice to Customer unless Customer provides Stryker Mako with a current, state issued exempt, resale, or right-to-self-assess certificate.

2. Shipment and Installation.

- 2.1. Shipping and Delivery. Shipping is F.O.B. destination. All Equipment will be shipped to the address indicated in the "ship to" portion of Customer's purchase order. Stryker Mako reserves the right to refuse to ship Equipment to third parties.
- 2.2. Site Preparation. Customer is responsible for providing the Equipment with a clean operating environment of suitable temperature and humidity pursuant to written specifications provided by Stryker Mako. Access to the installation site (and a suitable and safe space for storage of the Equipment before installation) will be provided by Customer at no charge as necessary for Stryker Mako to perform its obligations hereunder and Stryker Mako agrees to comply with any applicable, reasonable Customer policies regarding access to the installation site as provided prior to or upon execution of this Agreement. Any lifting equipment, building alterations, power supplies, power outlets, wiring, networking, or other work required by any applicable laws or by Stryker Mako in connection with the installation of the Equipment will be provided by Customer at its own expense. With the exception of FDA approval, Customer is responsible for obtaining all government approvals required, if any, for remediation of the installation location, the installation and use of the Equipment, including without limitation any certificate of need and zoning variances. Customer will complete all such activities diligently, will keep Stryker Mako notified periodically of the results of its efforts, and, upon request, will provide Stryker Mako with written confirmation of such approvals.

STRYKER MAKO OFFERS NO WARRANTY AND ASSUMES NO LIABILITY FOR THE FITNESS OR ADEQUACY OF THE PREMISES (OR THE UTILITIES AVAILABLE AT THE PREMISES) IN WHICH THE EQUIPMENT IS TO BE INSTALLED, USED, OR STORED, OTHER THAN THOSE ARISING FROM STRYKER MAKO'S FAILURE TO ACCURATELY SPECIFY THE LEVEL AND QUALITY OF PHYSICAL PREMISES AND UTILITIES NECESSARY FOR THE PROPER INSTALLATION AND OPERATION OF THE EQUIPMENT.

- 2.3. Installation. The Equipment will be installed by employees and or agents of Stryker Mako during "**Normal Business Hours**" (8:00 am to 5:00 pm, local time, excluding national holidays). Installation services include (a) connecting the Equipment to power outlets provided and installed by Customer prior to delivery of the Equipment and (b) testing the Equipment after installation to verify compliance with Stryker Mako's standard installation protocols. Installation will be considered complete for the purposes hereof upon verification that the Equipment substantially complies with Stryker Mako's published performance specifications, as evidenced by Stryker Mako's and Customer's signature on the RIO Site Installation Form.
 - 2.4. Installation Services. This Agreement includes standard installation services as outlined in section 2.3 only. Any additional time required, or delay(s) experienced in installing the Equipment resulting from the condition or location of Customer's premises, the condition or location of power supplies, outlets, networking, or wiring, delay(s) in completing site preparation, or any similar or dissimilar cause(s) will be at Customer's own expense. Any labor in excess of standard installation services and any overtime incurred by Stryker Mako employees and/or agents in respect of such additional time required or delay(s) experienced (as well as any extra labor or overtime work performed at the request of Customer) will be invoiced to and paid by Customer at then-prevailing Stryker Mako demand service rates.
 - 2.5. Acceptance. Customer's "**Acceptance**" of the Equipment and transfer of title thereto shall be deemed to have occurred upon Customer's (i) execution of this Agreement and (ii) delivery and (iii) installation of the Equipment at Customer's facility as set forth in Section 2.3 above. Should the purchase of the System be on a payment plan, title will transfer when the above is completed, along with the payment obligation on the total purchase price in Schedule A being fulfilled.
3. Use of Equipment. Customer agrees and covenants to only allow physicians that have been trained and certified by Stryker Mako and cleared by Customer to perform the applicable Robotic-arm Assisted Procedure to be performed to operate the Equipment (each, a "**Qualified Physician**"), each of whom shall be at all times fully authorized, licensed and credentialed under applicable law. Customer represents that each Qualified Physician is qualified and experienced in orthopedic surgery, has the skills and training necessary to operate the Equipment as contemplated, has been cleared by

the Customer to operate the Equipment, and is fully authorized, licensed and credentialed under applicable law, including regulations allowing for directed purchase of prescription-only devices. Customer further acknowledges and agrees that, while Stryker Mako has developed a training protocol for the Equipment which is, in Stryker Mako's opinion, reasonable to prepare Qualified Physician to use the Equipment in total knee, partial knee and total hip Robotic-arm Assisted Procedures, each Qualified Physician, together with the Customer, is solely responsible for determining the adequacy of his/her skills and training. The Parties agree that Customer may appoint additional Qualified Physicians in consultation with Stryker Mako. Customer further agrees and covenants that only personnel properly certified as trained by Stryker Mako, and cleared by Customer, for use of the RIO system shall at any time operate the Equipment. Customer acknowledges and agrees that the Stryker Mako's or an affiliate's personnel associated with a Robotic-arm Assisted Procedure are not licensed medical personnel, are not licensed to and do not practice medicine, and are, in every case of use of the Equipment and/or Services, only supplying a technology support role to Customer. Customer further agrees and covenants that any and all operation of the Equipment by certified personnel shall be at all times undertaken pursuant to and only consistent with the protocols and instructions set forth in the Equipment user manuals (or any successor documents thereof). Customer acknowledges that only Stryker Mako approved and supplied products (each a "**Product**") are FDA indicated for use with the Equipment. The Equipment shall only be operated at the Customer's facility where it is installed by Stryker Mako and shall not be moved from such facility absent the prior written consent of Stryker Mako.

4. **Products.**

4.1. **Products.** In performing clinical surgical procedures using the Equipment (each, a "**Robotic-arm Assisted Procedure**"), Customer acknowledges the purchase of the necessary Products for Robotic-arm Assisted Procedures shall be governed by an agreement between Customer and Stryker Mako's affiliate Howmedica Osteonics Corp.

4.2. **Discounts and Rebates.** Discounts and rebates received by Customer with respect to the Consumables under this Agreement are "discounts or other reductions in price" under the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(A)). Consistent with the Anti-Kickback Statute and the discount safe harbor (42 C.F.R § 1001.952(h)), if Customer reports its costs on a cost report pursuant to applicable state or federal cost reporting requirements, Customer shall fully and accurately report such discounts and other reductions in price in the applicable cost report. Customer also shall provide all information about such discounts and rebates as requested by any federal or state agency. Stryker Mako will provide Customer with sales and discount information to allow Customer to comply with this section, including sufficient rebate and pricing information to enable Customer to accurately report its actual costs for all purchases of Consumables made pursuant to this Agreement.

5. **Collaboration.** To the extent reasonable and in compliance with all applicable laws and regulations, Customer and Stryker Mako agree to collaborate on health care professional and patient educational outreach concerning robotic-arm assisted surgery for orthopaedic hip and knee procedures utilizing Stryker Mako equipment at Customer's facility. The collaboration shall include but is not limited to:

5.1. **Demonstrating Economic Value.** Customer agrees to make available orthopaedic surgical services data to Stryker Mako, including the gross number of robotic-arm assisted primary and revision knee and hip procedures and non-robotic-arm assisted primary and revision knee and hip procedures performed by Customer prior to and following the first Stryker Mako Robotic-arm assisted procedure.

5.2. **Online Resource Center.** Customer will receive password-protected access to an online resource center to assist with educational outreach efforts [available at: <https://makoresourcecenter.com/Mako/Login.aspx>]. The resource center provides information and materials regarding Equipment and Robotic-arm assisted surgery education and awareness for health care professionals and patients. Customer acknowledges it has ultimate control and responsibility for any and all materials it ultimately chooses to disseminate or utilize.

5.3. **Educational Outreach Practices.** The Parties agree to make an individual available to speak to Stryker Mako, at least once as part of the Equipment launch, regarding guidance for utilizing the Online Resource Center and standard practices regarding Stryker Mako's general educational outreach concerning Robotic-arm assisted surgery and Customer's educational outreach concerning the same at Customer's facility.

6. **Software.** All software associated with the Equipment is and shall remain the sole proprietary and confidential property of Stryker Mako. Use of such software is subject to the Software License Terms set forth as **Schedule C** to this Agreement.

7. **Equipment Warranty and Service.**

7.1. Any warranties provided with respect to the Equipment are as set forth in the Warranty and Service Terms set forth as **Schedule D** to this Agreement.

7.2. THE WARRANTIES REFERENCED IN THIS AGREEMENT ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE OR NON-INFRINGEMENT AND IN LIEU OF ANY

STRYKER MAKO CONFIDENTIAL

OTHER OBLIGATIONS OR LIABILITY ON THE PART OF STRYKER MAKO. STRYKER MAKO NEITHER ASSUMES (NOR HAS AUTHORIZED ANY PERSON TO ASSUME FOR IT) ANY OTHER WARRANTY OR LIABILITY IN CONNECTION WITH THE EQUIPMENT AND/OR SERVICES.

8. **Mako Program Analytics.** To assess the impact of the Equipment to Customer's service lines and to optimize the Equipment, Customer's purchase of the Equipment includes, through Stryker Mako's affiliate Stryker Performance Solutions, LLC ("SPS"), periodic assessments of Customer's self-reported and patient-reported outcome data ("**Mako Program Analytics**"). SPS will review such assessments with Customer, at minimum, on a quarterly basis. Stryker Mako and SPS will contact Customer after Equipment is Accepted by Customer pursuant to Section 2.5 of this Agreement. Customer's participation in the SPS Mako Program Analytics is conditioned on the execution of a no-additional charge agreement with SPS which shall become an amendment to and incorporated into this Agreement.
9. **Indemnification.** Stryker Mako agrees to indemnify Customer from any third-party liability and/or damages which Customer may suffer directly as a result of a defect in workmanship or design of the Equipment. This indemnification applies only if the instructions outlined in the Equipment's labeling, manual, and/or instructions for use are followed. This indemnification does not apply to liability and/or damages arising from: (a) an injury due to the negligence of any person other than an employee or agent of Stryker Mako; (b) the failure of any person other than an employee or agent of Stryker Mako to follow any instructions for use of the Equipment; or (c) the use of any product not purchased from Stryker Mako, or Equipment that has been modified, altered, reprocessed, or repaired by any person other than an employee or agent of Stryker Mako. Customer agrees to indemnify Stryker Mako against any claims or losses or injuries arising from (a), (b), or (c) above resulting from the negligence or willful misconduct of any employee or agent of Customer.
10. **Limitation of Liability.** EXCEPT IN CONNECTION WITH STRYKER MAKO'S INDEMNITY OBLIGATIONS UNDER SECTION 9 ABOVE, STRYKER MAKO SHALL HAVE NO LIABILITY TO ANY PARTY FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL, OR SPECIAL DAMAGES BY REASON OF ANY ACT OR OMISSION OR ARISING OUT OF OR IN CONNECTION WITH THE EQUIPMENT AND/OR THE SERVICES, OR THE SALE, DELIVERY, INSTALLATION, MAINTENANCE, TRAINING ON, OPERATION, PERFORMANCE, OR USE OF THE SAME, INCLUDING WITHOUT LIMITATION ANY LOSS OF USE, LOST REVENUES, LOST PROFITS, DAMAGE TO ASSOCIATED EQUIPMENT AND OTHER GOODS AND SERVICES OR TO FACILITIES, COSTS OF CAPITAL, COSTS OF SUBSTITUTE PRODUCTS, FACILITIES, OR SERVICES, COSTS OF REPLACEMENT POWER, COSTS ASSOCIATED WITH DOWN TIME, AND ANY SIMILAR AND DISSIMILAR LOSSES, COSTS, OR DAMAGES.
11. **Confidentiality.** Stryker Mako and Customer: (a) shall hold in strictest confidence this Agreement (including, without limitation, any and all pricing, discounts, purchase terms, and payment terms) and any information and materials which are related to the business of the other or are designated as proprietary or confidential, herein or otherwise, or which a reasonable person would consider to be proprietary or confidential information; (b) hereby covenant to not disclose such information to any third party without prior written authorization of the one to whom such information relates; and (c) agree that any breach or threatened breach of this section would cause irreparable harm, that a remedy at law will be inadequate to remedy such a breach or threatened breach, and that this section shall be enforceable by way of a restraining order or injunction, without the necessity of posting a bond, in addition to any other available legal remedies.

Notwithstanding anything to the contrary set forth herein in this Section 11, either Party shall have the right to disclose contract terms and conditions as well as pricing terms to those parties and/or consultants either Party has or will contract with or retain in the course of managing its business, provided that those parties/consultants agree in writing that they shall maintain the confidential information with no less a standard of care than the requirements contained herein and not use or divulge such confidential information to any third party, except as necessary for the discharge of their obligations to the disclosing Party or as required by law.

12. **Compliance Matters.**

12.1. **Compliance with Law.** In the performance of this Agreement, Customer and Stryker Mako shall at all times comply with all applicable federal, state, and local laws and regulations, including but not limited to, the Federal Food, Drug and Cosmetic Act, the Federal False Claims Act, and the Anti-Kickback Law.

12.2. **Discount Disclosure and Reporting.** Stryker Mako, as supplier, hereby informs Customer, as buyer, of Customer's obligation to make all reports and disclosures required by law or contract, including without limitation properly reporting and appropriately reflecting actual prices paid for each item supplied hereunder net of any discount (including rebates and credits, if any) applicable to such item on each Customer's Medicare cost reports, and as otherwise required under the Federal Medicare and Medicaid Anti-Kickback Statute and the regulations thereunder (42 CFR Part 1001.952(h)). Pricing under this Agreement may constitute discounts on the purchase of Equipment. Customer represents that it shall make all required reports and disclosures.

12.3. **Protection of Patient Information.** All medical information and/or data concerning specific patients (including, but not limited to, the identity of the patients), derived from or obtained during the course of the Agreement, including but not limited to protected health information ("PHI") as defined in regulations implementing the Health Insurance Portability and Accountability Act of 1996 and 45 C.F.R. parts 142 and 160-164, as amended ("HIPAA"), shall be

treated by both Parties as confidential so as to comply with all applicable state and federal laws and regulations regarding confidentiality of patient records, and shall not be released, disclosed, or published to any party other than as required or permitted under applicable laws. The Parties acknowledge that data provided pursuant to Section 5 of this Agreement shall not include any PHI, but that Stryker Mako requires access to identified session files and other diagnostic information residing on the Equipment from each Robotic-arm Assisted Procedure for the purpose of conducting regulatory investigations related to reports of potential adverse events or product complaints which are identified by the Qualified Physician, Customer personnel, or Stryker Mako employee present during a case. Stryker Mako is not a "business associate" of Customer, as the term "business associate" is defined by HIPAA regulations. To the extent Stryker Mako in the future becomes a business associate of Customer, the Parties agree to negotiate to amend the Agreement as necessary to comply with HIPAA, and if an agreement cannot be reached the Agreement will immediately terminate.

13. **Use of Name.** Stryker Mako hereby grants Customer the right to use Stryker Mako's name in furtherance of Customer's and Stryker Mako's collaboration efforts contemplated under Section 5 of this Schedule B; provided, however, that Stryker Mako reserves the right to terminate this right to use at any time in its sole discretion. Notwithstanding the foregoing, any use of Stryker Mako's name and trademarks must comply with Stryker Mako's Trademark Usage Policy. Stryker Mako agrees not to use any name or mark of Customer or to quote the opinion of any of Customer's employees in any advertising or other publicity, including in client lists or on Stryker Mako's website, without obtaining the prior written consent of Customer.
14. **Insurance.** Stryker Mako will maintain adequate general liability insurance, including coverage for products and completed operations, and workers compensation and employer's liability insurance against claims which arise out of Equipment purchased from Stryker Mako under this Agreement. Stryker Mako has the right to self-fund to comply with this requirement. When requested by Customer, Stryker Mako will furnish an insurance certificate signed by an authorized agent (facsimile signature acceptable) evidencing the above referenced insurance coverage.
15. **Miscellaneous.**
 - 15.1. Neither Party may assign or otherwise transfer its rights, duties and responsibilities under this Agreement without first receiving the written consent of the other Party, which in no case shall be unreasonably withheld. Notwithstanding the foregoing, no consent by Customer shall be required for an assignment by Stryker Mako pursuant to a merger, consolidation, sale of all or substantially all of the assets, or change of control of Stryker Mako or an affiliate. Customer agrees that Customer is prohibited from selling or transferring the Equipment under this Agreement and that Customer shall not otherwise enter into any agreement with a third party to transfer title and/or any right to use the Equipment without first receiving the written consent of Stryker Mako. Any purported assignment, sale or transfer in violation of this section shall be void.
 - 15.2. This Agreement shall be governed by and construed in accordance with the laws of the State of Michigan and the Parties consent and agree that any and all litigation arising from this Agreement will be conducted by state or federal courts located in State of Michigan. The invalidity or unenforceability of any provision hereof will not affect any other provision, and all terms and conditions will be construed in all respects as if any such invalid or unenforceable provision(s) were omitted. The failure of Customer or Stryker Mako at any time to require the performance of any obligation will not affect the right to require such performance at any time thereafter. The waiver of any remedy with respect to any default will not be taken as a waiver of any remedy for any succeeding default.
 - 15.3. Neither Party shall be liable for any delay or default caused by events beyond its control, including, without limitation, any acts of God, acts of suppliers or other third parties, acts of the other Party (or any of the other Party's employees, agents, or representatives), acts of civil or military authorities, terrorism, fires, floods, and other similar or dissimilar natural causes, riots, wars, sabotage, vandalism, embargoes, labor disputes, strikes, lockouts, delays in receiving any permits or licenses, delays caused by any laws, regulations, proclamations, ordinances, or any government action or inaction, delays caused by contractors and subcontractors, and any other cause or condition beyond such Party's control, and the time for performance of such Party's obligations hereunder shall be extended for the commercially reasonable period of time in the event of any delay or default for such cause(s).
 - 15.4. This Agreement may be executed in counterparts, each of which are deemed to be original, but all of which together constitute one and the same instrument. Copies of signatures sent by facsimile transmission or any other electronic means are deemed to be originals for purposes of execution and proof of this Agreement.
 - 15.5. This Agreement constitutes the entire agreement between the Parties concerning the subject matter of this Agreement and supersedes all prior negotiations and agreements between the Parties concerning the subject matter of this Agreement. Notwithstanding anything contained in this Agreement to the contrary, Stryker Mako will not participate in any Customer program, procedure, vendor credentialing, policy or directive requiring Stryker Mako personnel or agents to purchase surgical scrubs from Customer, Customer designee or any third-party vendor operating in Customer's facility. This Agreement may only be amended by written agreement of the Parties. In the event of an inconsistency or conflict between this Agreement and any purchase order, invoice, consignment agreement or related similar document, this Agreement will control.

15.6. The terms and conditions herein that by their terms are intended to survive the expiration or termination of this Agreement, including without limitation the provisions set forth in Sections 3–6, 8–12, 14, 15.1 and 15.2 of this Agreement, shall survive the execution and delivery of this Agreement and its expiration or termination.

SCHEDULE C SOFTWARE LICENSE AGREEMENT

1. Stryker Mako hereby grants to Customer a limited, personal, nonexclusive, and nontransferable license to use the computer software package (the "**Software**") necessary for the operation of the Equipment on the terms and conditions defined or referenced herein for so long as Customer may own or have valid access to the Equipment. THIS LICENSE DOES NOT EXTEND TO ANY MAINTENANCE OR SERVICE SOFTWARE SHIPPED TO OR LOCATED AT CUSTOMER'S PREMISES WHICH IS INTENDED TO ASSIST STRYKER MAKO EMPLOYEES OR AGENTS IN THE INSTALLATION, TESTING, SERVICE, AND MAINTENANCE OF THE EQUIPMENT.
2. THE LICENSE HEREBY GRANTED TO CUSTOMER DOES NOT INCLUDE ANY RIGHT TO USE THE SOFTWARE FOR PURPOSES OTHER THAN STANDARD OPERATION OF THE EQUIPMENT OR TO COPY, REPRODUCE, SELL, ASSIGN, TRANSFER, OR SUBLICENSE THE SOFTWARE FOR ANY PURPOSE, IN WHOLE OR IN PART, WITHOUT THE PRIOR WRITTEN CONSENT OF STRYKER MAKO, WHICH STRYKER MAKO MAY WITHHOLD IN ITS SOLE DISCRETION. If such permission is obtained, Customer agrees to apply Stryker Mako's copyright notice or other identifying legends to such copies or reproductions.
3. The rights herein granted to Customer shall not affect the exclusive ownership by Stryker Mako of the Software or of any trademarks, copyrights, patents, trade secrets, proprietary rights, or other property rights of Stryker Mako (or any of Stryker Mako's suppliers or licensors) pertaining to the Software.
4. Customer agrees that only authorized employees or agents of Customer will use the Software or have access to the same (or to any part thereof) and that none of Customer's employees or agents will disclose any part or all of the Software, or permit any part or all the same to be used by any person or entity other than those identified herein. Customer acknowledges that certain of Stryker Mako's rights may be provided from license agreements with third parties and, as such, Customer agrees to preserve the confidentiality of information provided to Stryker Mako under such third-party license agreements.
5. Customer is prohibited from making any modifications to the Software. If Customer modifies the Software in any manner, all warranties associated with the Software and the Equipment shall become null and void. If Customer or any of its officers, employees, or agents should make any revisions, enhancements, or improvements in the Software, Customer shall promptly disclose such improvements to Stryker Mako and shall become the property of Stryker Mako. Customer shall convey any and all title to such revisions, enhancements or improvements to Stryker Mako.
6. The Software is licensed to Customer provided that (a) Customer shall maintain the configuration of the Equipment as it was originally designed and manufactured and (b) the Equipment includes only those subsystems and components certified by Stryker Mako. The Software may not perform as intended on systems modified by personnel other than those under the direct supervision of Stryker Mako or on systems which include subsystems or components not certified by Stryker Mako. Stryker Mako does not assume any responsibility or liability with respect to unauthorized modification or substitution of subsystems or components.
7. IF CUSTOMER NO LONGER USES THE SYSTEM, CHOOSES TO "SWAP OUT" AND/OR "TRADE IN" THE EQUIPMENT OR REPAIR THE SOFTWARE, CUSTOMER IS SOLELY RESPONSIBLE FOR MAINTAINING POSSESSION AND CONTROL OF THE SOFTWARE UNTIL PROPERLY DELIVERED TO STRYKER MAKO OR ITS AGENTS. CUSTOMER IS RESPONSIBLE FOR PROVIDING IMMEDIATE WRITTEN NOTIFICATION TO STRYKER MAKO AT LEAST FOURTEEN (14) DAYS PRIOR TO ALLOWING ACCESS TO THE SAME BY ANY PARTY NOT RELATED TO, OR AFFILIATED WITH, CUSTOMER OR STRYKER MAKO.
8. OTHER THAN ANY WARRANTY PROVIDED HEREIN, AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, STRYKER MAKO AND ITS SUPPLIERS MAKE NO OTHER EXPRESS WARRANTIES UNDER THIS SOFTWARE LICENSE AGREEMENT, AND DISCLAIM ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT, AND ANY WARRANTY ARISING BY STATUTE, OPERATION OF LAW, COURSE OF DEALING OR PERFORMANCE, OR USAGE OF TRADE. STRYKER MAKO AND ITS LICENSORS DO NOT WARRANT THAT THE SOFTWARE WILL OPERATE UNINTERRUPTED OR THAT IT WILL BE FREE FROM DEFECTS OR THAT IT WILL MEET YOUR REQUIREMENTS.
9. Customer hereby acknowledges that the Software is or may be subject to one (1) or more export control laws or regulations, and agrees that it will not transfer, export or re-export the Software without complying with all applicable export control laws and regulations. Customer agrees it will not export or re-export the software to a national of a country listed in "Country Groups" D:1 or E:2 (as defined in the Export Administration Regulations), nor will Customer export or re-export the direct product of the software to such Country Groups without first obtaining a license from the U.S. Department of Commerce. The obligations in this paragraph shall survive the expiration or termination of this Agreement.

10. Customer shall cause each authorized user of the Software to abide by the terms and conditions of this Software License Agreement as if each were a party hereto.
11. This license shall continue for as long as Customer continues to use the Equipment, except that Stryker Mako may terminate this license in the event of any default by Customer. Customer agrees to cease use of, and return the Software and any authorized copies thereof to Stryker Mako immediately upon expiration or termination of this license.

SCHEDULE D WARRANTY AND SERVICE TERMS

This Schedule D (also referred to as these "Warranty and Service Terms") are hereby incorporated into the Agreement by and between Stryker Mako and Customer and relate to the warranty and maintenance of the Equipment and are subject to the terms and conditions contained elsewhere in this Agreement. In the event of a conflict between the other terms and conditions of the Agreement and of this Schedule D, the terms and conditions of this Schedule D shall govern. Capitalized terms used herein and not defined shall have the meanings ascribed to them elsewhere in the Agreement.

1. TERM

- 1.1 Warranty. Stryker Mako warrants that the Equipment will be free from defects in material and workmanship (the "Warranty") for one (1) year beginning upon Acceptance of the Equipment (the "Initial Warranty Period"). Stryker Mako's obligation under this Warranty shall be limited to repairing or replacing (at Stryker Mako's option) any part of the Equipment which, if properly installed, used and maintained, proves defective in material or workmanship within the Initial Warranty Period, provided that notice of any such defect and satisfactory proof thereof is promptly given by Customer to Stryker Mako. This Warranty does not apply to products normally consumed in operation of the Equipment or which have a normal life inherently shorter than the Initial Warranty Period.
- 1.2 Service. Stryker Mako will provide the services set forth in these Warranty and Service Terms for a period of four (4) consecutive years beginning on the expiration of the Initial Warranty Period on the originally installed Equipment (the "Service Period").

2. PRICE AND PAYMENT TERMS

- 2.1 Warranty. There is no charge for the Services (as defined below) contained in these Warranty and Service Terms during the Initial Warranty Period.
- 2.2 Service. Customer shall pay to Stryker Mako an annual service fee of \$90,000 (the "Annual Service Fee") for the Services contained in these Warranty and Service Terms during the Service Period. The Annual Service Fee shall be paid to Stryker Mako on or before the first day of each year of the Service Period.

3. DUTIES OF STRYKER MAKO. During the Initial Warranty Period and Service Period, Stryker Mako will provide the following services to Customer pursuant to these Warranty and Service Terms (referred to collectively as the "Services"):

- 3.1 Covered Services. Stryker Mako agrees to provide maintenance, including, without limitation, preventative maintenance, repair of the Equipment and Software, hardware reliability upgrades and software updates performed as applicable in Stryker Mako's sole discretion. The price for the Services includes all parts, labor and travel expenses, except those listed in Section 4 of these Warranty and Service Terms or set forth elsewhere herein. The Services shall be performed during Normal Business Hours. If Customer requests that Services be performed outside the Normal Business Hours, said Services will be furnished on a reasonable efforts' basis.
- 3.2 Response Time. On-site response will occur within twenty-four (24) hours during Normal Business Hours, unless Customer and Stryker Mako agree otherwise.
- 3.3 Loaners/Replacements. Should downtime of the Equipment continue for at least forty-eight (48) continuous hours, Stryker Mako will ship to Customer's facility within forty-eight (48) hours and install, at its sole expense, a loaner or replacement RIO® Robotic Arm Interactive Orthopedic system, unless Stryker Mako and Customer agree otherwise.
- 3.4 Exchanges. If, during any consecutive three (3) month period of the term of these Warranty and Service Terms, the Equipment experiences a recurring identified failure that Stryker Mako is unable to adequately repair (as determined by Stryker Mako in its reasonable discretion), Stryker Mako agrees to replace the Equipment at no cost to Customer.
- 3.5 Maintenance Parts. Stryker Mako will provide all necessary replacement parts to maintain the Equipment, except for the consumable items listed in Section 4 of these Warranty and Service Terms. Replacement parts will be either new parts or certified refurbished parts that in Stryker Mako's sole judgment are of equal performance and quality to new parts. All parts will be furnished on an exchange basis and all replaced parts become the sole property of Stryker Mako.
- 3.6 Service outside the 48 contiguous United States. Such service will be periodically scheduled in advance by Stryker Mako, in its sole discretion. If Customer requires an immediate response, Customer will pay all travel expenses of Stryker Mako personnel.
- 3.7 Scheduled Maintenance. Stryker Mako will provide scheduled maintenance for the Equipment at intervals determined by Stryker Mako in its sole discretion.

STRYKER MAKO CONFIDENTIAL

- 3.8 **Troubleshooting.** Stryker Mako may troubleshoot with one or more individuals designated by Customer via telephone to resolve a problem in lieu of traveling to Customer's facility to repair the Equipment.
- 3.9 **CT Validation.** Up to three (3) CT scan equipment validations shall be provided to Customer and included in the Services.
- 3.10 **Purchase of Surgical Scrubs.** Notwithstanding anything contained in these Warranty and Service Terms to the contrary, Stryker Mako will not participate in any Customer program, procedure, vendor credentialing, policy or directive requiring Stryker Mako personnel or agents to purchase surgical scrubs from Customer, Customer designee or any third-party vendor operating in Customer's facility.
4. **EXCLUSIONS FROM SERVICES.** The following actions and items are excluded from the Services:
- 4.1 **Misuse.** If Services are required as a result of, or arising from: (i) any intentional acts or negligence of Customer's employees, agents or invitees; (ii) anyone other than Stryker Mako authorized personnel attempting to repair or service the Equipment; (iii) use of equipment or devices not provided by Stryker Mako; (iv) misuse of the Equipment, including, without limitation, use of the Equipment for any application or function for which it was not designed; or (v) the loading of third-party software without the prior written approval of Stryker Mako, including, without limitation, device drivers not approved by Stryker Mako. Requests for Services related to misuse will be billed to Customer at Stryker Mako's then-current billable rates for travel, labor, and parts.
- 4.2 **Consumables and Accessories.** Consumables and accessories are defined as Burrs, Reamer Cups, Drapes, Bone Pins, Reflective Markers, Irrigation Tubes, Checkpoints, Leg Holder Boots, and other consumables.
- 4.3 **System Enhancements.** System upgrades, new features to the Equipment or Software not available at the time of purchase or new product applications, deemed by Stryker Mako to be major additions to the Equipment or Software.
- 4.4 **Electrical Work.** Electrical work external to the Equipment.
- 4.5 **Cosmetic Work.** Painting or refinishing, or the furnishing of the materials for this purpose.
- 4.6 **Moved Equipment.** Maintenance required in order to repair damage resulting from Customer's transportation of the Equipment.
- 4.7 **Data File Transfer and Recovery.** Stryker Mako shall demonstrate to Customer how to perform patient data file transfer, restoration and recovery prior to the first clinical case, and Customer warrants that it will not request Stryker Mako personnel to do same on Customer's behalf.
5. **RESPONSIBILITIES OF CUSTOMER**
- 5.1 **Access to Equipment.** - When Stryker Mako arrives at Customer's facility, Customer will provide Stryker Mako personnel reasonable access to the Equipment so that they may perform the Services. Customer may be billed at prevailing labor rates for lost time and travel if Stryker Mako personnel are not permitted reasonable access to the Equipment.
- 5.2 **Service Authorization.** Customer agrees to allow Stryker Mako personnel to service, upgrade and maintain the Equipment under the terms of these Warranty and Service Terms.
- 5.3 **Payment Terms.** Customer must pay the total amount due for the Services including all applicable federal, state and local taxes in accordance with the payment schedule set forth in these Warranty and Service Terms. Payment for Services outside normal business hours or for work performed other than Services that is outside the scope of these Warranty and Service Terms will be due and payable within thirty (30) days after the date of the applicable invoice.
- 5.4 **Renewal.** If Customer does not renew these Warranty and Service Terms to extend after the expiration of the Service Period, and subsequently requests Services in connection with the Equipment, all parts, labor, travel time and travel expenses will be billed to Customer at Stryker Mako's then-current billable rates. Customer shall notify Stryker Mako if it desires to renew these Warranty and Service Terms at least thirty (30) business days prior to the expiration of the Service Period.
- 5.5 **Patient Data Files.** - Integrity, maintenance, archive and backup of patient data files are the sole responsibility of Customer.

6. **EQUIPMENT LOCATION.** The Equipment is located at Customer's facility as described in the Agreement. Any subsequent resale or removal to a new location without Stryker Mako's prior written approval may result in immediate cancellation of these Warranty and Service Terms by Stryker Mako in its sole discretion.
7. **INSPECTION.** If (i) Customer does not utilize, terminates or fails to renew these Warranty and Service Terms and (ii) Customer elects to utilize or renew these Warranty and Service Terms at least thirty (30) days after such expiration or earlier termination, Stryker Mako, with reasonable notice to Customer, shall require Customer to pay the costs and expenses of a site inspection of the Equipment, performed by Stryker Mako personnel during Normal Business Hours, to determine the operating status of the Equipment. The inspection will be billed at Stryker Mako's then-current time and materials rate.






20210812 Brunswick Surgery Center- EQUIPMENT PURCHASE AGREEMENT.PDF

Final Audit Report

2021-08-12

Created:	2021-08-12
By:	Lou Ruggirello (lou.ruggirello@stryker.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA_HT9eHHkSvMeUy9SfYtMKobWbnSAxclQ

"20210812 Brunswick Surgery Center- EQUIPMENT PURCHASE AGREEMENT.PDF" History

-  Document created by Lou Ruggirello (lou.ruggirello@stryker.com)
2021-08-12 - 6:37:20 PM GMT- IP address: 52.154.71.15
-  Document emailed to Rick McDowell (rick.mcdowell@stryker.com) for signature
2021-08-12 - 6:38:19 PM GMT
-  Email viewed by Rick McDowell (rick.mcdowell@stryker.com)
2021-08-12 - 6:38:54 PM GMT- IP address: 174.211.32.5
-  Document e-signed by Rick McDowell (rick.mcdowell@stryker.com)
Signature Date: 2021-08-12 - 6:39:36 PM GMT - Time Source: server- IP address: 174.211.33.226
-  Agreement completed.
2021-08-12 - 6:39:36 PM GMT

From: [Tanya, Saporito](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Letter of No Review for Brunswick Surgery Center
Date: Monday, August 16, 2021 10:39:48 AM
Attachments: [Stryker MAKO Equipment Purchase Agreement 2021 08 12 Executed.pdf](#)

Tanya Saporito, J.D.

Project Analyst

[Division of Health Service Regulation](#), Certificate of Need
[NC Department of Health and Human Services](#)



Help protect your family and neighbors from COVID-19.

[Know the 3 Ws. Wear. Wait. Wash.](#)

#StayStrongNC and get the latest at nc.gov/covid19

Office: 919-855-3873

Tanya.saporito@dhhs.nc.gov

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

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

From: James Rouse <james.rouse@emergeortho.com>

Sent: Friday, August 13, 2021 5:02 PM

To: Tanya, Saporito <tanya.saporito@dhhs.nc.gov>

Cc: Anna Weaver <Anna.Weaver@brunswickurgerycenter.com>; David B Meyer
(dmeyer@keystoneplanning.com) <dmeyer@keystoneplanning.com>

Subject: [External] Letter of No Review for Brunswick Surgery Center

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Ms Saporito,

Please see the attached Request for No Review Determination sent on behalf of Anna Weaver, Administrator, for Brunswick Surgery Center.

Thank you,

Jim

James Rouse, CPA | *Chief Administrative Officer*
EmergeOrtho - Wilmington
3787 Shipyard Blvd, Wilmington, NC 28403
Phone: +1 (910) 332-1521 ext 31228
james.rouse@emergeortho.com | www.EmergeOrtho.com



CONFIDENTIALITY NOTICE: The information contained in this transmission may contain privileged and confidential information, including patient information protected by federal and state privacy laws. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution, or duplication of this communication is strictly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

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.