

Monterey County Board of Supervisors

Board Order

168 West Alisal Street, 1st Floor Salinas, CA 93901 831.755.5066

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A motion was made by Supervisor Wendy Root Askew, seconded by Supervisor Chris Lopez with Supervisor Mary L. Adams voting no to approve Consent Calendar Item Numbers 16 through 30:

Agreement No.: A-16197

- a. Ratify execution by the Chief Executive Officer for Natividad Medical Center (NMC) a month-to-month short term rental agreement with Brainlab, Inc. for a software-based guided neurosurgery system, for a total amount not to exceed \$100,000 and with an effective date of July 21, 2022.
- b. Authorize the Chief Executive Officer for Natividad Medical Center (NMC) or his designee to execute a twelve (12) month lease agreement with Brainlab, Inc. for a software-based guided neurosurgery system for an amount not to exceed \$330,762 (intended to replace the short term rental agreement), with an agreement term effective when signed by both parties.
- c. Approve the NMC Chief Executive Officer's recommendation to accept non-standard indemnification, insurance, and limitations on liability provisions within both agreements.

PASSED AND ADOPTED on this 21st day of March 2023, by roll call vote:

AYES: Supervisors Alejo, Church, Lopez, and Askew

NOES: Supervisor Adams

ABSENT: None

I, Valerie Ralph, Clerk of the Board of Supervisors of the County of Monterey, State of California, hereby certify that the foregoing is a true copy of an original order of said Board of Supervisors duly made and entered in the minutes thereof of Minute Book 82 for the meeting March 21, 2023.

Dated: March 23, 2023 File ID: A 23-061

Agenda Item No.: 17

Valerie Ralph, Clerk of the Board of Supervisors County of Monterey, State of California

Emmanuel H. Santos, Deputy

Rental Agreement

This Rental Agreement (hereinafter "Agreement") is made by and between the County of Monterey, a political subdivision of the State of California, for the provision of services at Natividad Medical Center (Collectively "County" and hereinafter referred to as "Customer"), a general acute care teaching hospital wholly owned and operated by the

"Equipment" means the Brainlab surgical navigation system utilizing for cranial and spine cases and corresponding hardware accessories, disposables and instruments provided to Customer under this Agreement and as specified in Quotation Number QN-NMCSCU-CSY-115.

"Fee" means \$27,563.44 per month.

"Products" means the Equipment and Software.

"Services" means the services performed in connection with the use of the Products, as specified in Quotation Number QN-NMCSCU-CSY-115.

"Software" means the software products delivered with or integrated in the Equipment, namely cranial and spine navigation software, as specified in Quotation Number QN-NMCSCU-CSY-115.

"Term" means twelve (12) months, commencing upon the Effective Date.

Scope, Application, and Term.

- During the Term Customer shall have use of the Products and receive Services from Brainlab for use of the Products. Brainlab will utilize commercially reasonable efforts to be available for all requested cases.
- All Products and Services are furnished pursuant and subject to the terms of this Agreement only. Customer's terms and conditions in any order documentation pre-printed or otherwise, shall not apply.

Customer shall remove all Customer data and information stored on the Equipment at the end of the Term. In the event Customer data or information remains on the Equipment, the Customer data or information may be deleted or removed without liability to Customer.

IV. Use and Operation

- Brainlab support personnel must be present for each use of the Products, otherwise a full acceptance protocol, signed by Customer, will be required.
- Customer warrants that the Products will be operated only by personnel who have participated in user training.

- All title, interest, and rights to patents, copyrights, trademarks, and any other worldwide intellectual property V.Intellectual Property and/or proprietary rights related to the Products and/or any deliverables provided by the Services are owned by, and shall remain the property of, Brainlab, its affiliates and/or its licensors, as applicable.
- Brainlab grants Customer a limited, non-exclusive, non-transferable license to use the Software in accordance with its intended use, on the Equipment on which it is delivered or on which it is installed for the Term.
- Nothing in this Agreement shall entitle Customer to copy, decompile, or allow third parties access to the
- If a Product contains a Microsoft product ("Embedded System"), Customer shall not use internet browsing functionality with the Embedded System to connect to and access cloud hosted applications, such as Microsoft Office 365. This section is a requirement that Brainlab must comply with based on its Microsoft OEM Customer License Agreement for Embedded Systems.

VI. Ownership and Title

- The Products shall at all times be and remain the sole and exclusive property of Brainlab notwithstanding that the Products may now be, or hereafter become, in any manner affixed or attached to, or embedded in, or permanently resting upon real property or any improvement thereon or attached in any manner to what is permanent as by means of cement, plaster, nails, bolts, screws or otherwise. Customer shall not remove any labeling affixed to the Products. Customer shall have no right, title or interest therein or thereto except as to the use thereof subject to the terms and conditions of this Agreement. Customer shall not permit its rights or interests hereunder to be subject to any lien, charge or encumbrance and shall keep the Products free and clear of any and all liens, charges and encumbrances which may be levied against or imposed upon Customer for
- Without the prior written consent of Brainlab, Customer shall not make any alterations, additions or improvements to the Products. All additions and improvements of whatsoever kind or nature made to the

Products shall be deemed accessions thereto, shall belong to and immediately become the property of Brainlab and shall be returned to Brainlab with the Products upon completion of the Term.

Customer hereby assumes and shall bear the entire risk of loss of, theft of, damage to, or destruction of the Products except when caused by Brainlab or Brainlab's subcontractors.

VII. Fees, Payment Terms

- The Fee shall be due monthly with all invoices being due net thirty (30) days from the date County Auditor-Controller receives from Natividad a Brainlab invoice certified for payment. Natividad shall certify the invoice for payment promptly upon receipt but in no event less than five (5) days after receipt thereof.
- 2. Customer shall pay as directed by Brainlab or reimburse Brainlab upon demand for all taxes, including but not limited to sales, use, or property taxes (exclusive of federal and state taxes based on or measured solely by Brainlab's net income), fees, charges or assessments, of whatsoever kind, whether based on the fee, rent or levied, assessed or imposed upon the Products or upon or in respect of the manufacture, purchase, delivery, ownership, leasing, use, return or other disposition of the Products, now or hereafter levied, assessed or imposed under the authority of a federal, state or local taxing jurisdiction, regardless of when and by whom payable ("Taxes and Fees"). Customer authorizes Brainlab to add to the amount of the Fee, and shall pay, any Taxes and Fees that may be imposed on or measured by such fees at any time. In the event Customer is a tax exempt entity, Customer shall notify Brainlab in writing and provided written evidence of such status.

VIII. Confidentiality

- 1. The term Confidential Information means all trade secrets, business methods, know-how, inventions and other financial, business or technical information disclosed by or for a party in relation to this Agreement, but not including any information the receiving party can demonstrate is (a) rightfully furnished to it without restriction by a third party, (b) already in its possession prior to receipt or is generally available to the public without breach of this Agreement, including a disclosure by County of this Agreement required under the California Public Records Act, or (c) independently developed by it without reliance on such information. Except for those and other specific rights granted or implied by this Agreement (or to comply with any legal, regulatory, law enforcement or similar requirement or investigation), the receiving party shall not access, reproduce, use or disclose any of the other's Confidential Information without its written consent, and shall use reasonable care to protect the other's Confidential Information from unauthorized access, use and disclosure (including by ensuring that its employees and contractors who access any Confidential Information have a need to know for the permitted purpose and are bound by written obligations that are at least as protective as this Agreement). Each party shall be responsible for any breach of confidentiality by its employees and contractors.
- 2. The Parties will comply with the applicable provisions of HIPAA and the HITECH Act and the terms of the Business Associate Agreement attached hereto as Exhibit A.
- For the improvement of products and customer support Brainlab shall be entitled to collect statistical data stored on Products used by Customer. This data will be stored anonymous and used exclusively for internal purposes.

IX. Disclaimer of Warranty, Limitations of Liability, Insurance

- The Products are provided without warranty and ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE, USE, OR APPLICATION, ARE HEREBY EXPRESSLY DISCLAIMED AND WAIVED.
- 2. CUSTOMER ACKNOWLEDGES THAT THE PRODUCTS ARE OF A SIZE, DESIGN, TYPE AND MANUFACTURE SELECTED BY CUSTOMER AND EXCEPT AS EXPRESSLY SET FORTH HEREIN, BRAINLAB HAS NOT MADE AND DOES NOT HEREBY MAKE ANY AGREEMENT, REPRESENTATION OR WARRANTY WITH RESPECT TO THE MERCHANTABILITY, CONDITION, QUALITY OR SUITABILITY OF THE PRODUCTS IN ANY RESPECT OR IN CONNECTION THEREWITH FOR THE PURPOSES AND USES OF CUSTOMER, OR ANY OTHER AGREEMENT, REPRESENTATION OR WARRANTY OF ANY KIND OR CHARACTER, EXPRESS OR IMPLIED, WITH RESPECT TO THE EQUIPMENT.
- 3. The total liability of Brainlab arising under this Agreement for any reason shall not exceed \$500,000.
- 4. Neither party shall be liable for any loss of use, revenue or anticipated profits, loss of stored or transmitted data, or for incidental, unforeseen, special, punitive or consequential damages arising out of or in connection with this Agreement or the use of the Products.
- 5. NOTHING IN THIS AGREEMENT SHALL BE TAKEN TO EXCLUDE OR LIMIT EITHER PARTY'S LIABILITY (A) FOR FRAUD OR FRAUDULENT MISREPRESENTATION; (B) FOR GROSS NEGLIGENCE, INTENTIONAL, WILLFUL, OR CRIMINAL MISCONDUCT; (C) FOR DEATH, PERSONAL INJURY, OR TANGIBLE PROPERTY DAMAGE CAUSED BY ITS GROSS NEGLIGENCE; (D) BREACH OF CONFIDENTIALITY IN SECTION VII.1; OR (E) TO THE EXTENT THAT SUCH EXCLUSION OR LIMITATION IS NOT OTHERWISE PERMITTED BY LAW.
- 6. Brainlab shall not be liable for any damages whatsoever caused by (i) the use of the Products prior to successful performance of the acceptance test if the Products are used without Brainlab personnel present; (ii) any use of the Products prior to applicable training; (iii) any use, operation, service, modification of the Products contrary to

relevant manuals, written warnings, automated warnings, or instructions of Brainlab personnel; or (iv) the use of the Products in conjunction with third party products, unless this use has been expressly authorized in writing by Brainlab.

Brainlab shall carry the insurance coverage listed in Exhibit B.

X. Governing Law, Jurisdiction

These terms and conditions as well as all contractual and other legal relationships between the parties shall be governed by the laws of the State of California, USA.

Nothing in this agreement shall prevent Brainlab from seeking injunctive relief or other legal remedy to prevent unauthorized copying, disclosure, use, retention, or distribution of Brainlab's intellectual property or for breach of Sections V (Intellectual Property), VI (Ownership and Title), or VII (Confidentiality).

XI. General Provisions

No right or remedy conferred herein is exclusive of any other right or remedy conferred hereunder or at law or in equity, by statute or otherwise, and may be exercised concurrently or separately from time to time. The waiver by either party of any term or condition of this Agreement or any Equipment Use in any one instance shall not be deemed or construed to be a waiver of such term or condition for any similar instance in the future or any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement of either party.

The provisions of Sections I (Definitions), V (Intellectual Property), VI (Ownership and Title), VIII (Confidentiality), IX (Disclaimer of Warranty, Limitations of Liability, Insurance), X (Governing Law, Jurisdiction),

and XI (General Provisions) shall survive termination of this Agreement.

If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable or shall render this entire Agreement to be unenforceable or invalid, such offending provision shall be of no effect and shall not affect the validity of the remainder of this Agreement or any of its provisions. The invalid or unenforceable clause will be replaced by the valid clause that generally comes closest to the commercial intention of the invalid clause.

This Agreement constitutes the entire agreement between the parties as to the subject matter hereof, and has priority over all documents, oral consents or understandings, express or implied, between the parties before the conclusion of this Agreement with respect to the subject matter hereof. None of the terms of this Agreement shall be amended or modified except in a written instrument signed by the parties hereto.

County of Monterey	Brainlab, Inc. (Brainlab)
Charles R. Harris, CEO for Natividad Date	Sear M. Clark, President Stan M. Clark Date 1099286F42F545D 2/24/2023 1:00 PM PST

Approved as to form.

Approved as to fiscal terms.

Chief Deputy County Counsel

Stacy Saetta -CDECE1899F444A9

2/7/2023 | 9:26 AM PST

Chief Deputy Auditor-Controller

Jennifer Farsyth 4F7E657875454AE

2/8/2023 | 8:44 AM PST

EXHIBIT A

BUSINESS ASSOCIATE AGREEMENT

See attached executed Business Associate Agreement, dated July 22, 2022

EXHIBIT A

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("BAA") effective <u>July 22</u>, 2022 ("Effective Date"), is entered into by and among between the County of Monterey, a political subdivision of the State of California, for the provision of services at Natividad Medical Center ("Covered Entity") and <u>Brainlab, Inc.</u> ("Business Associate") (each a "Party" and collectively the "Parties").

RECITALS

- A. WHEREAS, Business Associate provides certain Services for Covered Entity that may involve the Use and Disclosure of Protected Health Information ("PHI") that is created, received, transmitted, or maintained by Business Associate for or on behalf of Covered Entity.
- B. WHEREAS, The Parties are committed to complying with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), and their implementing regulations, including the Standards for the Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E (the "Privacy Rule"), the Breach Notification Standards, 45 C.F.R. Part 160 and 164 subparts A and D (the "Breach Notification Rule"), and the Security Standards, 45 C.F.R. Part 160 and Part 164, Subpart C (the "Security Rule"), (collectively "HIPAA"), all as amended from time to time.
- C. WHEREAS, The Parties are also committed to complying with the California Confidentiality Laws (defined below).
- D. WHEREAS, To the extent that Business Associate is performing activities in connection with covered accounts for or on behalf of Covered Entity, the Parties are also committed to complying with applicable requirements of the Red Flag Rules issued pursuant to the Fair and Accurate Credit Transactions Act of 2003 ("Red Flag Rules").
- E. WHEREAS, The Privacy and Security Rules require Covered Entity and Business Associate to enter into a business associate agreement that meets certain requirements with respect to the Use and Disclosure of PHI. This BAA, sets forth the terms and conditions pursuant to which PHI, and, when applicable, Electronic Protected Health Information ("EPHI") shall be handled, in accordance with such requirement.

NOW THEREFORE, in consideration of the mutual promises below and the exchange of information pursuant to this BAA, the Parties agree as follows:

AGREEMENT

1. DEFINITIONS

- 1.1 All capitalized terms used in this BAA but not otherwise defined shall have the meaning set forth in the Privacy Rule, the Breach Notification Rule, or the Security Rule.
- (a) "Breach" shall have the same meaning as "breach" as defined in 45 C.F.R. § 164.402 and shall mean the access, acquisition, Use, or Disclosure of PHI in a manner not permitted under the Privacy Rule that compromises the privacy or security of the PHI; the term "Breach" as used in this BAA shall also mean the unlawful or unauthorized access to, Use or Disclosure of a patient's "medical information" as defined under Cal. Civil Code § 56.05(j), for which

notification is required pursuant to Cal. Health & Safety Code 1280.15, or a "breach of the security of the system" under Cal. Civil Code §1798.29.

- (b) "California Confidentiality Laws" shall mean the applicable laws of the State of California governing the confidentiality of PHI or Personal Information, including, but not limited to, the California Confidentiality of Medical Information Act (Cal. Civil Code §56, et seq.), the patient access law (Cal. Health & Safety Code §123100 et seq.), the HIV test result confidentiality law (Cal. Health & Safety Code §120975, et seq.), the Lanterman-Petris-Short Act (Cal. Welf. & Inst. Code §5328, et seq.), and the medical identity theft law (Cal. Civil Code 1798.29).
- (c) "Protected Health Information" or "PHI" shall mean any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual; (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information that can be used to identify the individuals, and (iii) is provided by Covered Entity to Business Associate or created, maintained, received, or transmitted by Business Associate on Covered Entity's behalf. PHI includes EPHI.
- (d) "Services" shall mean the services for or functions on behalf of Covered Entity performed by Business Associate pursuant to a Services Agreement between Covered Entity and Business Associate to which this BAA applies.

PERMITTED USES AND DISCLOSURES OF PHI

Unless otherwise limited herein, Business Associate may:

- (a) Use or Disclose PHI to perform Services for, or on behalf of, Covered Entity, provided that such Use or Disclosure would not violate the Privacy or Security Rules, this BAA, or California Confidentiality Laws;
- (b) Use or Disclose PHI for the purposes authorized by this BAA or as otherwise Required by Law;
- (c) Use PHI to provide Data Aggregation Services for the Health Care Operations of Covered Entity, if required by the Services Agreement and as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B);
- (d) Use PHI if necessary for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted by 45 C.F.R. § 164.504(e)(4)(i);
- (e) Disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted under 45 C.F.R. § 164.504(e)(4)(ii), provided that Disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is Disclosed that it will remain confidential and be Used or further Disclosed only as Required by Law or for the purpose for which it was Disclosed to the person, and that such person will notify the Business Associate of any instances of which such person is aware that the confidentiality of the information has been breached;

- (f) Use PHI to report violations of law to appropriate Federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1); and
- (g) De-identify any PHI obtained by Business Associate under this BAA in accordance with 45 C.F.R. § 164.514 and Use or Disclose such de-identified information only as required to provide Services pursuant to the a Services Agreement between the Parties, or with the prior written approval of Covered Entity.

3. RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI

- 3.1. <u>Responsibilities of Business Associate</u>. With regard to its Use and/or Disclosure of PHI, Business Associate shall:
- Notify the Privacy Officer of Covered Entity, in writing, of: (i) any Use and/or Disclosure of the PHI that is not permitted or required by this BAA; (ii) any Security Incident of which Business Associate becomes aware; and (iii) any suspected Breach. Such notice shall be provided within five (5) business days of Business Associate's discovery of such unauthorized access, acquisition. Use and/or Disclosure. Notwithstanding the foregoing, the Parties acknowledge the ongoing existence and occurrence of attempted but ineffective Security Incidents that are trivial in nature, such as pings and other broadcast service attacks, and unsuccessful login attempts. The Parties acknowledge and agree that this Section 3.1(a) constitutes notice by Business Associate to Covered Entity of such ineffective Security Incidents and no additional notification to Covered Entity of such ineffective Security Incidents is required, provided that no such Security Incident results in a Breach. A ransomware attack shall not be considered an ineffective Security Incident and shall be reported to Covered Entity, irrespective of whether such Security Incident results in a Breach. Business Associate shall investigate each Security Incident or unauthorized access, acquisition, Use, or Disclosure of PHI, or suspected Breach that it discovers and shall provide a summary of its investigation to Covered Entity, upon request. If Business Associate or Covered Entity determines that such Security Incident or unauthorized access, acquisition, Use, or Disclosure, or suspected Breach constitutes a Breach, then Business Associate shall comply with the requirements of Section 3.1(a)(i) below;
- (i) Business Associate shall provide a supplemental written report in accordance with 45 C.F.R. § 164.410(c), which shall include, to the extent possible, the identification of each individual whose PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, Used or Disclosed during the Breach, to Covered Entity without unreasonable delay, but no later than five (5) business days after discovery of the Breach:
- (ii) Covered Entity shall have sole control over the timing and method of providing notification of such Breach to the affected individual(s), the appropriate government agencies, and, if applicable, the media. Business Associate shall reasonably assist with the implementation of any decisions by Covered Entity to notify individuals or potentially impacted individuals;
- (b) In consultation with the Covered Entity, Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of such improper access, acquisition, Use, or Disclosure, Security Incident, or Breach. Business Associate shall take prompt corrective action, including any action required by applicable State or federal laws and regulations relating to such Security Incident or non-permitted access, acquisition, Use, or Disclosure. Business Associate shall reimburse Covered Entity for its reasonable actual and direct costs and expenses in providing any required notification to affected individuals, appropriate government agencies, and, if necessary the media, including, but not limited to, any administrative costs associated with providing notice, printing and mailing costs, public relations costs, attorney fees, and costs of mitigating the harm (which may include the costs of obtaining up to one year of

credit monitoring services and identity theft insurance) for affected individuals whose PHI or Personal Information has or may have been compromised as a result of the Breach. In no event, and notwithstanding anything to the contrary herein, shall Business Associate's liability or obligations under this Section 3 exceed \$1,000,000 per incident;

- (c) Implement appropriate administrative, physical, and technical safeguards and comply with the Security Rule to prevent Use and/or Disclosure of EPHI other than as provided for by this BAA;
- (d) Obtain and maintain a written agreement with each of its Subcontractors that creates, maintains, receives, Uses, transmits or has access to PHI that requires such Subcontractors to adhere to the substantially the same restrictions and conditions with respect to PHI that apply to Business Associate pursuant to this BAA;
- (e) Make available all internal practices, records, books, agreements, policies and procedures and PHI relating to the Use and/or Disclosure of PHI received from, created, maintained, or transmitted by Business Associate on behalf of Covered Entity to the Secretary of the Department of Health and Human Services ("Secretary") in a time and manner designated by the Secretary for purposes of determining Covered Entity's or Business Associate's compliance with the Privacy Rule;
- (f) Document Disclosures of PHI and information related to such Disclosure and, within thirty (30) days of receiving a written request from Covered Entity, provide to Covered Entity such information as is requested by Covered Entity to permit Covered Entity to respond to a request by an individual for an accounting of the Disclosures of the individual's PHI in accordance with 45 C.F.R. § 164.528. At a minimum, the Business Associate shall provide the Covered Entity with the following information: (i) the date of the Disclosure; (ii) the name of the entity or person who received the PHI, and if known, the address of such entity or person; (iii) a brief description of the PHI Disclosed; and (iv) a brief statement of the purpose of such Disclosure which includes an explanation of the basis for such Disclosure. In the event the request for an accounting is delivered directly to the Business Associate, the Business Associate shall, direct the Individual to contact the Covered Entity directly. The Business Associate shall implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section;
- (g) Disclose to its Subcontractors or other third parties, and request from Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder;
 - (h) If all or any portion of the PHI is maintained in a Designated Record Set of Covered Entity maintained by Business Associate, if any:
- (i) Upon ten (10) days' prior written request from Covered Entity, provide access to the PHI to Covered Entity to meet a request by an individual under 45 C.F.R. § 164.524. If Business Associate receives a request for access to PHI directly from an Individual, Business Associate shall direct the Individual to contact Covered Entity directly; and
- (ii) Upon ten (10) days' prior written request from Covered Entity, make PHI available to Covered Entity to make any amendment(s) to the PHI that Covered Entity directs (for so long as Business Associate maintains such information in the Designated Record Set) pursuant to 45C.F.R. § 164.526. If Business Associate receives a request for amendment to PHI directly from an Individual, Business Associate shall direct the Individual to contact Covered Entity directly;
- (i) To the extent that Business Associate carries out one or more of Covered Entity's obligations under the Privacy Rule, Business Associate shall comply with the applicable

requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligations;

- (j) Unless prohibited by law, notify the Covered Entity within five (5) days of the Business Associate's receipt of any request or subpoena for PHI. To the extent that the Covered Entity decides to assume responsibility for challenging the validity of such request, the Business Associate shall reasonably cooperate with the Covered Entity in such challenge; and
- (k) Maintain policies and procedures materially in accordance with State Confidentiality Laws and industry standards designed to ensure the security and integrity of the Covered Entity's data and protect against threats or hazards to such security.

3.2 Business Associate Acknowledgment.

- (a) Business Associate acknowledges that, as between the Business Associate and the Covered Entity, all PHI shall be and remain the sole property of the Covered Entity.
- (b) Business Associate further acknowledges that it is obligated by law to comply, and represents and warrants that it shall comply, with HIPAA and the HITECH Act. Business Associate shall comply with all California Confidentiality Laws, to the extent that such state laws are not preempted by HIPAA or the HITECH Act.
- (c) Business Associate further acknowledges that uses and disclosures of protected health information must be consistent with NMC's privacy practices, as stated in NMC's Notice of Privacy Practices. The current Notice of Privacy Practices can be retrieved online at: http://www.natividad.com/quality-and-safety/patient-privacy. Business Associate agrees to review the NMC Notice of Privacy Practices at this URL at least once annually while doing business with NMC to ensure it remains updated on any changes to the Notice of Privacy Practices NMC may make.
- 3.3 Responsibilities of Covered Entity. Covered Entity shall, with respect to Business Associate:
- (a) Provide Business Associate a copy of Covered Entity's notice of privacy practices ("Notice") currently in use;
- (b) Notify Business Associate of any changes to the Notice that Covered Entity provides to individuals pursuant to 45 C.F.R. § 164.520, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI;
- (c) Notify Business Associate of any changes in, or withdrawal of, the consent or authorization of an individual regarding the Use or Disclosure of PHI provided to Covered Entity pursuant to 45 C.F.R. § 164.506 or § 164.508, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI; and
- (d) Notify Business Associate of any restrictions on Use and/or Disclosure of PHI as provided for in 45 C.F.R. § 164.522 agreed to by Covered Entity, to the extent that such restriction may affect Business Associate's Use or Disclosure of PHI.
- (e) Covered Entity shall not cause Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA if done directly by Covered Entity.

- (f) Covered Entity represents that, to the extent Covered Entity provides PHI to Business Associate, such PHI is the minimum necessary PHI for the accomplishment of Business Associate's purpose.
- (g) Covered Entity represents that, to the extent Covered Entity provides PHI to Business Associate, Covered Entity has obtained the consents, authorizations and/or other forms of legal permission required under HIPAA and other applicable law.

4. TERM AND TERMINATION

- 4.1 Term. This BAA shall become effective on the Effective Date and shall continue in effect unless terminated as provided in this Section 4. Certain provisions and requirements of this BAA shall survive its expiration or other termination as set forth in Section 5 herein.
- 4.2 <u>Termination</u>. If Covered Entity determines in good faith that Business Associate has breached a material term of this BAA, Covered Entity may either: (i) immediately terminate this BAA and any underlying Services Agreement; or (ii) terminate this BAA and any underlying Services Agreement within thirty (30) days of Business Associate's receipt of written notice of such breach, if the breach is not cured to the satisfaction of Covered Entity.
- 4.3 <u>Automatic Termination</u>. This BAA shall automatically terminate without any further action of the Parties upon the termination or expiration of Business Associate's provision of Services to Covered Entity.
 - Effect of Termination. Upon termination or expiration of this BAA for any reason, Business Associate shall return or destroy all PHI pursuant to 45 C.F.R. § 164.504(e)(2)(ii)(J) if, and to the extent that, it is feasible to do so. Prior to returning the PHI, Business Associate shall recover any PHI in the possession of its Subcontractors. To the extent it is not feasible for Business Associate to return or destroy any portion of the PHI, Business Associate shall: (i) retain only that PHI which is necessary for Business Associate to continue its proper management and administration or carry out its legal responsibilities; (ii) return to Covered Entity the remaining PHI that the Business Associate maintains in any form; (iii) continue to extend the protections of this BAA to the PHI for as long as Business Associate retains PHI; (iv) limit further Uses and Disclosures of such PHI to those purposes that make the return or destruction of the PHI not feasible and subject to the same conditions as set out in Section 2 above, which applied prior to termination; and (vi) return to Covered Entity or destroy the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.

5. MISCELLANEOUS

- 5.1 <u>Survival</u>. The respective rights and obligations of Business Associate and Covered Entity under the provisions of Sections 2.1, 4.4, 5.7, 5.8, and 5.11 shall survive termination of this BAA until such time as the PHI is returned to Covered Entity or destroyed. In addition, Section 3.1(i) shall survive termination of this BAA, provided that Covered Entity determines that the PHI being retained pursuant to Section 4.4 constitutes a Designated Record Set.
- 5.2 <u>Amendments: Waiver</u>. This BAA may not be modified or amended, except in a writing duly signed by authorized representatives of the Parties. To the extent that any relevant provision of HIPAA, the HITECH Act, or California Confidentiality

Laws is materially amended in a manner that changes the obligations of the Parties, the Parties agree to negotiate in good faith appropriate amendment(s) to this BAA to give effect to the revised obligations. Further, no provision of this BAA shall be waived, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

- 5.3 <u>No Third Party Beneficiaries</u>. Nothing express or implied in this BAA is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.
- 5.4 Notices. Any notices to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below.

 If to Business Associate, to:

Brainlab, Inc. Attn: Privacy Officer 5 Westbrook Corporate Center, Suite 1000 Westchester, Illinois 60154 With a copy to Corporate Counsel at same address above

If to Covered Entity, to:

Natividad Medical Center Attn: Compliance/Privacy Officer 1441 Constitution Blvd. Salinas, CA 93906 Phone: 831-755-4111

Phone: 831-755-4111 Fax: 831-755-6254

Each Party named above may change its address and that of its representative for notice by the giving of notice thereof in the manner hereinabove provided. Such notice is effective upon receipt of notice, but receipt is deemed to occur on next business day if notice is sent by FedEx or other overnight delivery service.

- 5.5 <u>Counterparts: Facsimiles.</u> This BAA may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.
- 5.6 Relationship of Parties. Notwithstanding anything to the contrary in the Services Agreement, Business Associate is an independent contractor and not an agent of Covered Entity under this BAA. Business Associate has the sole right and obligation to supervise, manage, contract, direct, procure, perform, or cause to be performed all Business Associate obligations under this BAA.
- 5.7 <u>Choice of Law: Interpretation.</u> This BAA shall be governed by the laws of the State of California. Any ambiguities in this BAA shall be resolved in a manner that allows Covered Entity and Business Associate to comply with the Privacy Rule, the Security Rule, and the California Confidentiality Laws.
- 5.8 Applicability of Terms. This BAA applies to all present and future Service Agreements and Business Associate relationships, written or unwritten, formal or informal, in which Business Associate creates, receives, transmits, or maintains any PHI for or on behalf of Covered Entity in any form whatsoever. This BAA shall automatically be incorporated in all subsequent agreements between Business Associate and Covered Entity involving the Use or Disclosure of PHI whether or not specifically referenced therein. In the event of any conflict or

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inconsistency between a provision of this BAA and a provision of any other agreement between Business Associate and Covered Entity, the provision of this BAA shall control unless the provision in such other agreement establishes additional rights for Business Associate or additional duties for or restrictions on Business Associate with respect to PHI, in which case the provision of such other agreement will control.

- 5.9 Insurance. In addition to any general and/or cyber liability insurance required of Business Associate, Business Associate agrees to obtain and maintain, at its sole expense, liability insurance. Such insurance coverage will be maintained for the term of this BAA, and a copy of a certificate evidencing the policy shall be provided to Covered Entity at Covered Entity's written request.
- 5.10 <u>Legal Actions</u>. Promptly, Business Associate shall advise Covered Entity of any actual or potential action, proceeding, regulatory or governmental orders or actions, or any material threat thereof that becomes known to it that may directly affect the interests of Covered Entity or jeopardize this BAA, and of any facts and circumstances that may be pertinent to the prosecution or defense of any such actual or potential legal action or proceeding, except to the extent prohibited by law.
- 5.11 <u>Audit or Investigations</u>. Promptly, Business Associate shall advise Covered Entity of any audit, compliant review, or complaint investigation by the Secretary or other state or federal agency related to compliance with HIPAA, the HITECH Act, or the California Confidentiality Laws directly related to Covered Entity PHI.

IN WITNESS WHEREOF, each of the undersigned has caused this BAA to be duly executed in its name and on its behalf as of the Effective Date.

BUSINESS ASSOCIATE	COVERED ENTITY Docusigned by	
By	By: Charles Harris	
Print Name Sean M. Clark	Charles Harris Print Name:	_
Print Title President	Print Title:	_
Date: July 22, 2022	Date:	_

EXHIBIT B - INSURANCE REQUIREMENTS

Brainlab, Inc. (BRAINLAB) agrees to adhere to the following Monterey County Insurance Requirements:

Prior to commencement of this Agreement, BRAINLAB shall provide a "Certificate of Insurance" certifying that coverage as required herein has been obtained.

This verification of coverage shall be sent to Monterey County's Contracts/Purchasing Department at Natividad, unless otherwise directed. BRAINLAB shall not receive a "Notice to Proceed" with the work under this Agreement until it has obtained all insurance required and County has approved such insurance. This approval of insurance shall neither relieve nor decrease the liability of BRAINLAB.

Qualifying Insurers. All coverages except surety, shall be issued by companies which hold a current policy holder's alphabetic and financial size category rating of not less that A-VII, according to the current Best's Key Rating Guide or a company of equal financial stability that is approved by Customer's Contracts/Purchasing Director.

Insurance Coverage Requirements: Without limiting BRAINLAB's duty to indemnify, BRAINLAB shall maintain in effect throughout the term of this Agreement a policy or policies of insurance with the following minimum limits of liability:

Commercial General Liability Insurance, including but not limited to premises and operations, including coverage for Bodily Injury and Property Damage, Personal Injury, Contractual Liability, Broad form Property Damage, Independent contractors, Products and Completed Operations, with a combined single limit for Bodily Injury and Property Damage of not less than \$1,000,000 per occurrence.

Business Automobile Liability Insurance, covering all motor vehicles, including owned, leased, non-owned, and hired vehicles, used in providing services under this Agreement, with a combined single limit for Bodily Injury and Property Damage of not less than \$500,000 per occurrence.

Workers' Compensation Insurance, If BRAINLAS employs other in the performance of this Agreement, in accordance with California Labor Code section 3700 and with Employer's Liability limits not less than \$1,000,000 each person, \$1,000,000 each accident and \$1,000,000 each disease.

OTHER INSURANCE REQUIREMENTS:

All insurance required by this Agreement shall be issued and executed by an admitted insurer authorized to transact insurance business in the State of California. Unless otherwise specified by this Agreement, all such insurance shall be written on an occurrence basis, or, if the policy is not written on an occurrence basis, such policy with the coverage required herein shall continue in effect for a period of three years following the date BRAINLAB completes its performance of services under this Agreement.

BRAINLAB shall use commercially reasonable efforts to provide COUNTY with notice in writing at least thirty days in advance of any endorsed reduction in coverage or limit, cancellation, or intended non-renewal thereof. Each policy shall provide coverage for BRAINLAB and additional insured with respect to claims arising from each subContractors. if any, performing work under this Agreement, or be accompanied by a certificate of insurance from each subContractors showing each subContractors has identical insurance coverage to the above requirements

Prior to the execution of this Agreement by COUNTY, BRAINLAB shall file certificates of insurance with COUNTY's Contracts/Purchasing Department at Natividad, showing that the BRAINLAB has in effect the insurance required by this Agreement. The BRAINLAB shall file a new or amended certificate of insurance within five calendar days after any change is made in any insurance policy, which would alter the information on the certificate then on file. Acceptance or approval of insurance shall in no way modify or change the indemnification clause in this Agreement, which shall continue in full force and effect.

BRAINLAB shall at all times during the term of this Agreement maintain in force the insurance coverage required under this Agreement and shall send, without demand by COUNTY, annual certificates to COUNTY's Contracts/Purchasing Department. If the certificate is not received by the expiration date, COUNTY shall notify BRAINLAB and BRAINLAB shall have five calendar days to send in the certificate, evidencing no lapse in coverage during the interim. Failure by BRAINLAB to maintain such insurance is a default of this Agreement, which entitles COUNTY, at its sole discretion, to terminate the Agreement immediately



Brainlab, Inc.

5 Westbrook Corporate Center Suite 1000

Westchester · IL 60154 · USA

phone. +1 708 409 1343 fax: +1 708 409 1619

Natividad Medical Center 1441 Constitution Boulevard Salinas, California, 93906-3100 United States

Westchester, January 5, 2023 Quotation QN-NMCSCU-CSY-115

Delivery:

DDP (Incoterms 2020)

Payment Terms:

30% Order Confirmation, 60% Delivery, 10% Acceptance

Payment terms periodic annually upon acceptance

The prices and conditions set forth in this quotation are valid for a period of 90 days from the date of its issue. The attached terms with the title 'Standard Terms and Conditions-Brainlab, Inc.' are hereby incorporated and form an integral part of this quotation.

Refurbished Curve MSA

1	E19901	PLATFORM CURVE DUAL NAVIGATION STATION (REFURBISHED)	
1	E19901	CURVE DUAL NAVIGATION STATION (REFURBISHED)	
		CONTRACTOR OF THE STATE OF THE	3
		ACCESSORIES CRANIAL	
2	B1 1011	ACCESSORY PACKAGE CRANIAL BASIC	1
3	18370	Z-TOUCH LASER REGISTRATION POINTER	1
4	B11004	VARIOGUIDE PACKAGE	1
		ACCESSORIES SPINE & TRAUMA	
5	B23506	ACCESSORY PACKAGE SPINE BASIC	1
6	B23510	ACCESSORY PACKAGE SPINE FOR DRILLING	1
7	B23526	PEDICLE ACCESS NEEDLE SET FOR MANUAL CALIBRATION	1
8	B23507	ACCESSORY PACKAGE SPINE FOR UNIVERSAL INSTRUMENT INTEGRATION	1
9	B23518	ACCESSORY PACKAGE SPINE FOR MINIMALLY INVASIVE SURGERY	1
		DISPOSABLES IMAGE GUIDED SURGERY	
10	55797	DISPOSABLE STYLET (10 PCS, PRE-CALIBRATED)	1
11	55846	DISPOSABLE TROCAR INSERT FOR PEDICLE ACCESS NEEDLE (5 PCS)	2
12	53153	DISPOSABLE CLIP-ON REMOTE CONTROL (20 PCS)	1
13	41773	DISPOSABLE REFLECTIVE MARKER SPHERE (90 PCS)	4
14	4 17 79	DISPOSABLE BIOPSY NEEDLE 1.8 MM / 235 MM (5 PCS)	2

≉ BRAINLAB

Pos Art No	Qescription	Coy manths
	IMPLEMENTATION SERVICES SURGERY INSTALLATION AND CONFIGURATION BRAINLAB CONNECTED CARE	1
16 81001-11	INSTALLATION CURVE NAVIGATION SYSTEM	
18 41839-65	SPARE PARTS SPINE & TRAUMA 3 DRILL BIT 2.4 MM AO SHANK (SUPPORTS DEPTH CONTROL) 5 DRILL BIT 2.6 MM AO SHANK (SUPPORTS DEPTH CONTROL) 5 DRILL BIT 3.2 MM AO SHANK (SUPPORTS DEPTH CONTROL)	5 5 5
20 50780	FREIGHT, INSURANCE AND FEES FREIGHT, INSURANCE AND FEES	1

Clinical Support

Ommoor		City, months
Pos Art.No	Description	
21 89020-0	SERVICE AGREEMENT SURGERY 7 CLINICAL CONSULTATION IMAGE GUIDED SURGERY - 12 CONSECUTIVE MONTHS	(1))

Software

Solition			r od in
Pos. Art No.	Description		
	ELEMENTS SUBSCRIPTION	4	12
22 26415	ELEMENTS VIEWER SMART LAYOUT SPINE SUBSCRIPTION	10	
23 26250	ELEMENTS TRAJECTORY PLANNING CRANIAL SUBSCRIPTION	1	12
24 26200	ELEMENTS SMARTBRUSH SUBSCRIPTION	10	12
25 26217	ELEMENTS IMAGE FUSION SUBSCRIPTION	7	12
26 26388	ELEMENTS VIEWER 3D SUBSCRIPTION	1	12
	ELEMENTS SCREW PLANNING SPINE SUBSCRIPTION	1	12
27 26711	ORIGIN DATA MANAGEMENT SUBSCRIPTION	1	12
28 26201	ORIGIN DATA MANAGEMENT GODGOTHI TOO		
	NAVIGATION CRANIAL	g.	40
29 26650	NAVIGATION SOFTWARE CRANIAL SUBSCRIPTION	1	12
30 26645	REGISTRATION SOFTWARE CRANIAL SUBSCRIPTION	1	12
	NAVIGATION SOFTWARE CRANIAL - EXTENSION SURFACE MATCHING	1	12
31 26648	REGISTRATION SUBSCRIPTION		
	INSTRUMENT SETUP SOFTWARE CRANIAL/ENT SUBSCRIPTION	1	12
32 22228	ALIGNMENT SOFTWARE VARIOGUIDE SUBSCRIPTION	1	12
33 26529	ALIGNMENT SUFTWARE VARIOGOIDE SOBSSITE TO		

ℱBRAINLAB

Pos. Art No.	Description.	Oly.	Period n
A STATE OF THE STA	NAVIGATION SPINE & TRAUMA		
34 26509	NAVIGATION SOFTWARE SPINE & TRAUMA 3D SUBSCRIPTION	1	12
35 22271	INSTRUMENT SETUP SOFTWARE SPINE SUBSCRIPTION	3	12
36 26513	REGISTRATION SOFTWARE - EXTENSION SURFACE MATCHING SPINE SUBSCRIPTION	1	12
37 26781	REGISTRATION SOFTWARE SPINE SUBSCRIPTION	1	12
Service Contra	act		D d i .
Pag. Art.No	Description	Qly,	Period in
	SERVICE AGREEMENT SURGERY		
38 81000-40	HARDWARE SUPPORT PACKAGE CURVE DUAL DISPLAY (SYSTEM AGE 6	1	12

Total Capital Investment + Total Operating Expenses

YEARS)

308,178.00 USD

(excl. tax)

Technical Quote Review done by

T. Kröning

Scott Casey

Area Account Manager

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Thomas Kroenung

Technical Quote Review Specialist