

County of Monterey

Board of Supervisors Chambers 168 W. Alisal St., 1st Floor Salinas, CA 93901

Board Report

File #: A 15-088, Version: 1

- a. Authorize the Deputy Purchasing Agent for Natividad Medical Center (NMC) to execute an Agreement with Brainlab, Inc. for Knee Surgery Navigation Equipment including Hardware, Software, Maintenance and Training at NMC for an amount not to exceed \$204,411.86 for the period April 28, 2015 through April 27, 2020.
- b. <u>Approve the NMC Chief Executive Officer's recommendation to accept non-standard indemnification, limitations on liability, and limitations on damages provisions within the Agreement.</u> (REVISED VIA SUPPLEMENTAL)

RECOMMENDATION:

It is recommended the Board of Supervisors:

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- b. <u>Approve the NMC Chief Executive Officer's recommendation to accept non-standard indemnification, limitations on liability, and limitations on damages provisions within the Agreement.</u>

SUMMARY/DISCUSSION:

Computer Assisted Orthopedic surgery (navigation) is being utilized for total knee replacements (TKR) across Monterey County. Using navigation allows higher accuracy in positioning the knee implants (replacement parts). Higher accuracy increases long term survival and functioning of the implants resulting in a better quality of life for patients.

It is necessary to purchase the equipment as the orthopedic surgeons prefer performing TKR's with the navigation system.

Equipment to be purchased includes the following:

- Navigation platform which includes the portable display cart and separate mobile camera cart allowing for flexible positioning of the camera.
- The Origin Data Management operating system which facilitates intelligent and automatic synchronization of data between platforms. (Allows PACS access).
- Knee Accessories which include instruments and equipment needed for the surgery.

Services included in the purchase include onsite clinical application and training for NMC's Surgery staff. Two one day sessions will be offered giving the participants the opportunity to gain basic proficiency in the use of the equipment and software. Each one day session includes the following:

- 3 two hour training sessions for surgeons and staff (maximum of 6 participants).
- Continuing education credits.

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• Educational materials.

The Extended Warranty package is included which provides:

- 24/7 Hotline Remote support.
- Preventative Maintenance inspection.
- Navigation installation.

Finally the monthly license fee allows NMC access to all future updates and upgrades and ongoing support by Brainlab's clinical specialists. Deliverables will be monitored with receipt of the equipment and presentation of the educational sessions. Functioning of the software support or maintenance will be monitored in the QRR incident reporting system and by the Director of Surgical Services.

The need for total knee replacements is projected to grow as the population in the United States ages. NMC's surgical volume has seen steady growth in this procedure over the last year. At NMC, the surgeons need the equipment to assure proper positioning of the implants. In a 2011 article by Schmitt et al, the stated reason for more than 50% of total knee revisions (a second surgery) is the implants being improperly positioned. This equipment improves the patient's quality of life and provides the patient with a better post - operative outcome.

OTHER AGENCY INVOLVEMENT:

County Counsel has reviewed and approved this Agreement as to legal form but not as to liability and risk provisions. The NMC contracts team engaged in lengthy negotiations with BrainLab, Inc. but the vendor would not agree to the County's standard insurance and indemnification provisions. BrainLab, Inc. agreed to include mutual indemnification clause but would not comply with the insurance endorsement requirements, which would have added the County of Monterey as an additional insured. Brainlab, Inc. agreed to a specific provision indemnifying the County for intellectual property infringement, as well as to the addition of malware and non-infringement warranties. On the other hand, Brainlab, Inc. insisted on monetary limitations for liability for negligence, strict liability, breach of contract, and breach of warranty. Likewise, Brainlab Inc. would not agree to the indemnification clause in the BAA. Therefore County Counsel approves the Agreement as to legal form only but no as to risk or liability.

The Auditor-Controller has reviewed and approved the Agreement as to payment provisions. The Agreement has also been reviewed and approved by NMC's Finance Committee on March 26th, 2015 and by its Board of Trustees on April 3, 2015.

FINANCING:

The cost for this Agreement is \$204,411.86 of which \$137,427.33 is included in the Fiscal Year 2014-15 Adopted Budget. \$12,925 will be included in the FY15-15 Recommended Budget. Amounts for remaining years of the Agreement will be included in those budgets as appropriate. The majority of the total cost for the Agreement is for new equipment to be purchased this fiscal year. Costs for equipment maintenance going forward will be billed over a sixty (60) month period. There is no impact to the General Fund.

Prepared by: Alexander Di Stante, Chief of Surgery, 783-2526 Approved by: Gary R. Gray, DO, Interim Chief Executive Officer, 783-2504

Attachments: Agreement BAA

Attachments on file with the Clerk of the Board