



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

March 7, 2018

Robbie Roberts, Manager, Market Planning
WakeMed
3000 New Bern Avenue
Raleigh NC 27612

No Review

Record #: 2532
Facility Name: WakeMed Raleigh Campus
FID #: 943528
Business Name: WakeMed
Business #: 2018
Project Description: Acquire robotic surgical equipment
County: Wake

Dear Mr. Roberts:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of February 27, 2018 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that 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.

However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Michael J. McKillip
Project Analyst



Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR



WakeMed 
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, North Carolina 27610
919-350-8000

February 27, 2018

VIA ELECTONIC MAIL

Michael J. McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Request for "No Review" to Acquire Globus ExcelsiusGPS Surgical System at WakeMed Raleigh Campus

Dear Mr. McKillip:

This letter is to inform you of WakeMed's intent to acquire one unit of the Globus Medical ExcelsiusGPS Surgical System for use at the Raleigh Campus. ExcelsiusGPS is a robotic guidance and navigation system that supports minimally invasive and open orthopaedic and neurosurgical cases, particularly spinal procedures. The equipment is designed to minimize radiation exposure, streamline workflow, and assist in implant placement. By purchasing this new equipment, WakeMed will continue to provide quality of care and technology that meet the needs of its patients. Please see Attachment 1 for product information. The proposed acquisition will not change current hospital operations, and no additional construction or support space is necessary to accommodate this medical equipment.

WakeMed believes this project should not be subject to certificate of need review. The proposed equipment purchase would not exceed the cost threshold of \$750,000 for major medical equipment, defined in N.C.G.S. §131E-176(14o).

The ExcelsiusGPS system's purchase price will be \$735,000. Please see Attachment 2 for the vendor quote. WakeMed is requesting a determination from the Healthcare Planning and Certificate of Need Section as to whether it may proceed with purchasing this equipment without a CON.

Thank you for your attention to this matter. If you have any questions or require additional information, please do not hesitate to contact me at 919-350-8023.

Sincerely,



Robbie Roberts
Manager, Market Planning



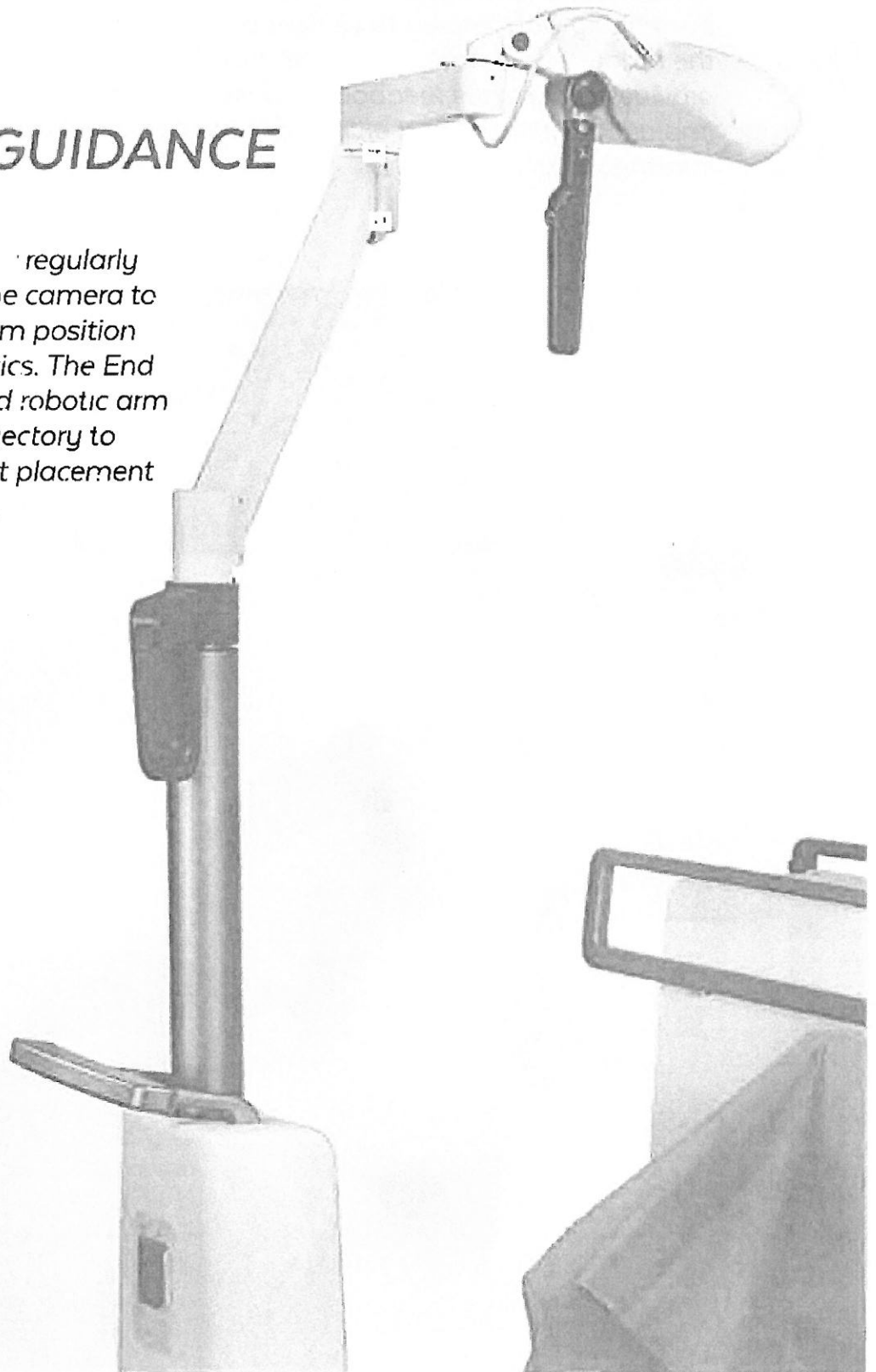
ExcelsiusGPS™

REVOLUCIONA Y ROBOTIC NAVIGATION

Established for navigation. The system is designed to be intuitive and compatible with surgical workflow. Real-time tracking of instruments and multiple, virtual, adjustable fields of view provide guidance throughout the procedure.

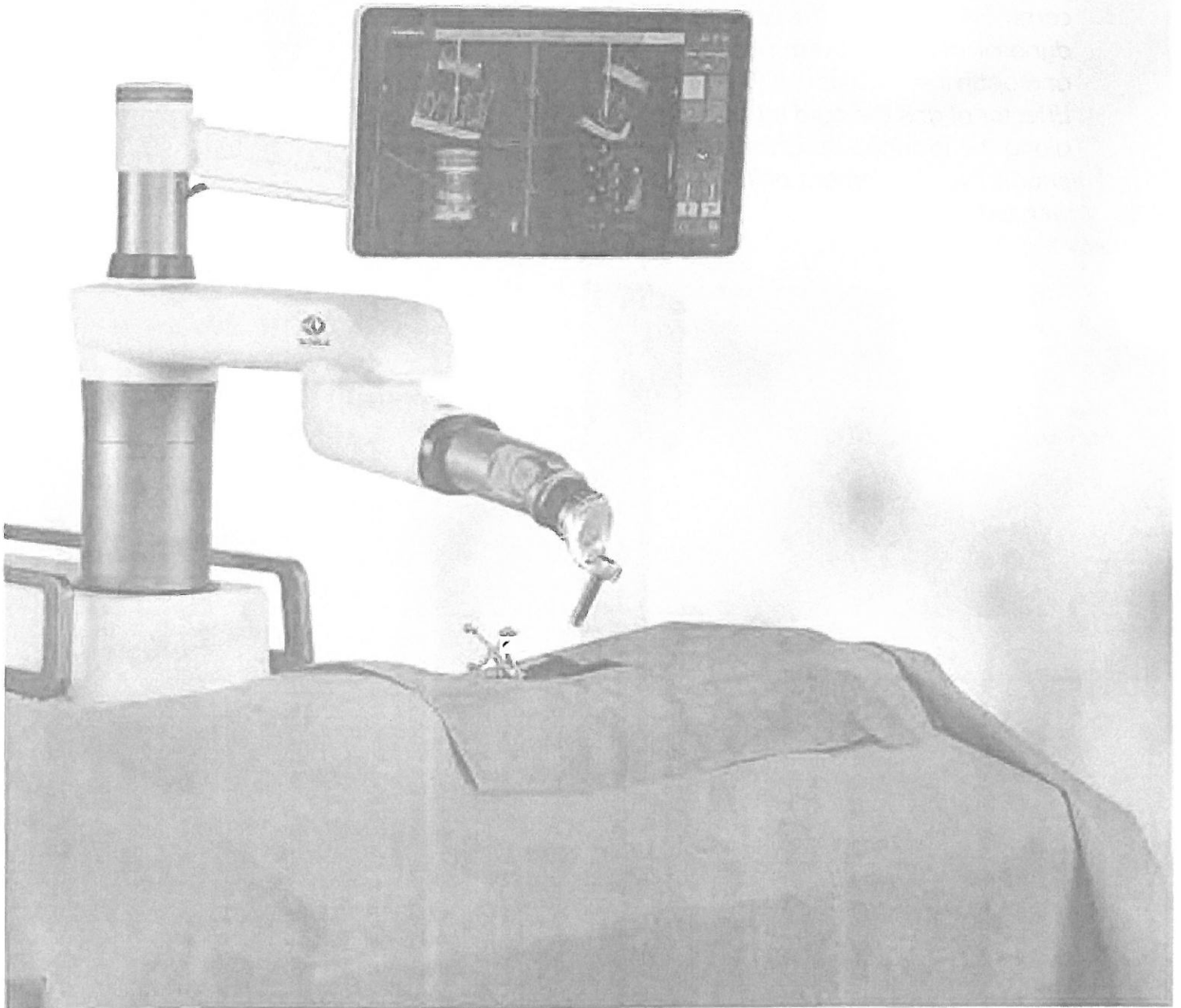
ROBOTIC GUIDANCE

The active robot regularly communicates with the camera to dynamically adjust arm position and optimize kinematics. The End Effector aligns the rigid robotic arm along the planned trajectory to enable precise implant placement with GPS instruments.



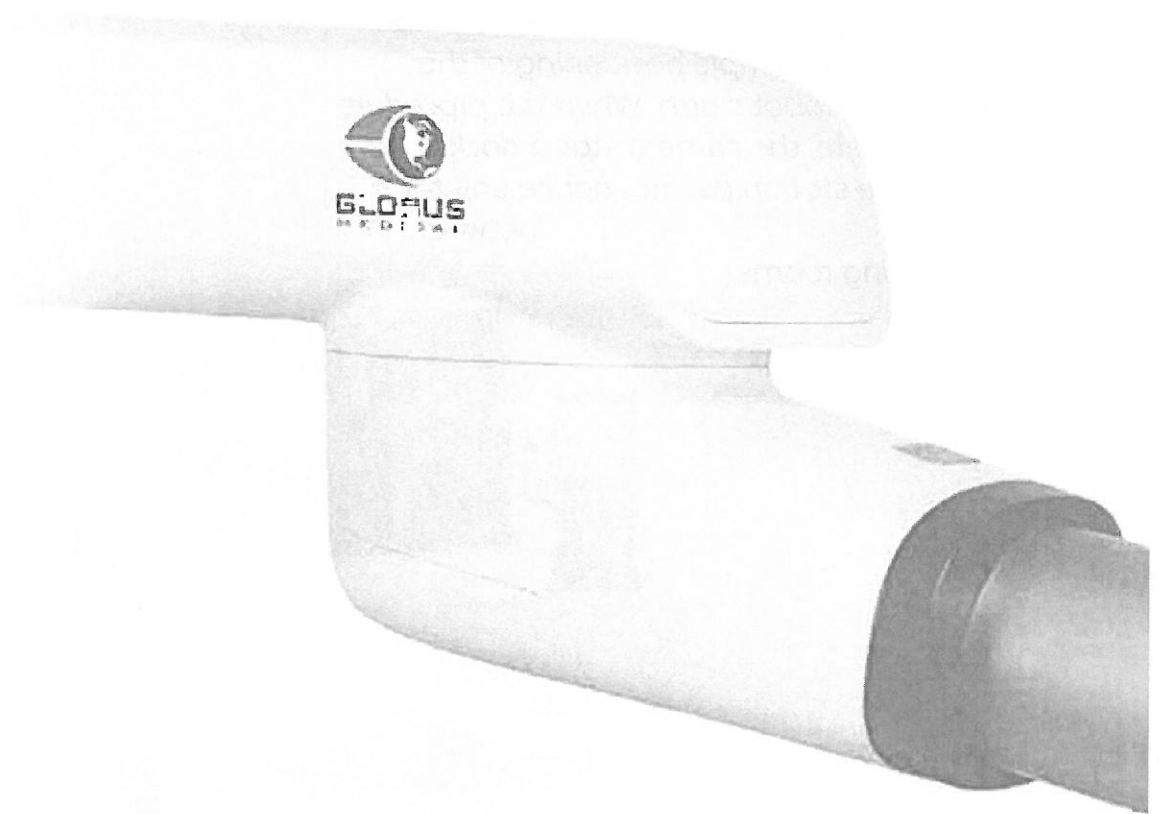
NAVIGATION

ExcelsiusGPS™ provides - of instrument and implant positioning with respect to patient anatomy which may help reduce the amount of radiation required throughout the procedure. Navigation provides continuous feedback and visualization. Surgeons confirm final implant positioning and ultimately receive more information to make informed clinical decisions



Setup for ExcelsiusGPS™ involves system draping and simple positioning of the frameless robotic arm. When the procedure is complete, the camera stand docks into the base station as one mobile unit for transport between operating rooms





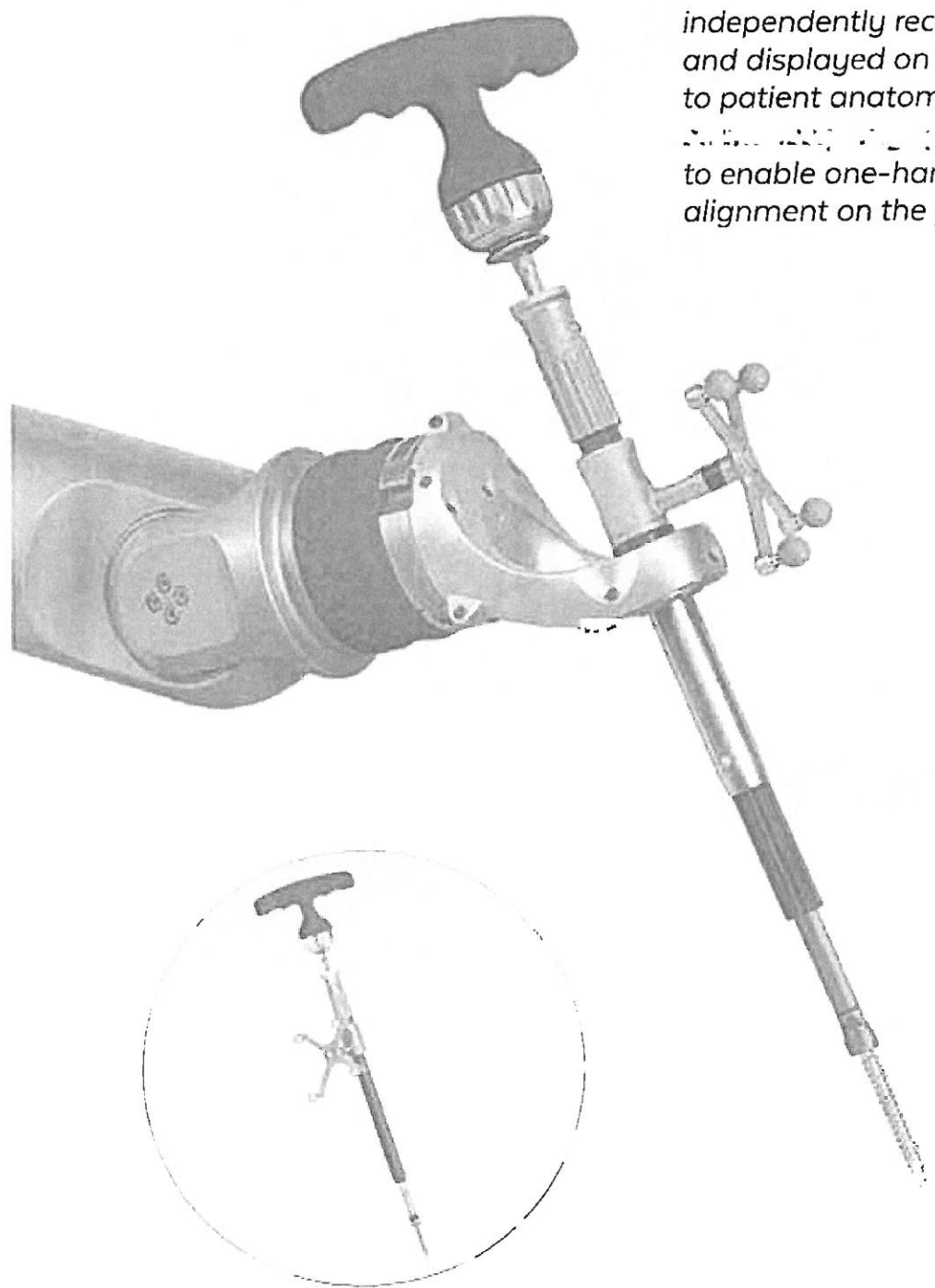
RIGID ROBOTIC ARM

The robotic arm automatically moves along the planned trajectory. The rigidity of the robotic arm allows for precise and rapid component insertion on steep trajectories.



GPS INSTRUMENTS

Each GPS instrument has an array independently recognized by the camera and displayed on the monitor in relation to patient anatomy. The instruments have a T-handle and a three-pronged array to enable one-handed use and to confirm alignment on the planned trajectory.





IMAGING COMPATIBILITY

Excels:usGPS™ is ...
This
versatility allows the system to fit into any
surgical workflow and enables planning
and navigation 2D or 3D.

M E D I C A L

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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REGD RNS - UK Limited
28 Trinity Place, Halesley, Somerset, BS48 4MU England

GMBRC213
08.17 Rev A



Globus Medical
 2580 General Ambrose Avenue
 Audubon, PA 13402
 (610) 930-1500
QUOTE

Quote Information

Quote ID	15646_121317
Quote Date	12/13/2017
Expiration Date	12/22/2017
Regional Sales Manager	Jessica Sullivan
Phone Number	704-519-9874
Email	jsullivan@globusmedical.com

Company Information

Hospital Name	WakeMed Raleigh
Customer ID	15646
City	Raleigh
State	NC
Contact Name	Jessica Sullivan
Telephone	704-519-9874

Items

Part Number	Description	Qty
	Excelsius GPS, 120V	1
	Tablet PC, Excelsius GPS	1
	Fluoroscopy Registration Fixture, 9"	1
	End Effector, 15MM	3
	Spine Software Module	1
	Fluoroscopy Software Module	1

Part Number	Description	Qty
	Arm Drape, 10 CT	1
	Monitor Drape, 20 CT	1
	Bone Clamp, with Surveillance Marker, Long	
	Dynamic Reference Base Array	
	Verification Probe	
	Clamp Driver	
	Intra-Op CT Registration Fixture	
	Intra-Op CT Registration Fixture Pivoting Arm	
	Scalpel Handle, GPS, 15mm	
	Awl Array, 15mm	
	MIS Awl, GPS	

Part Number	Description	Qty
	Navigation, GPS	
	CREO & CREO AMP, GPS	2
	CREO MIS, GPS	2
	CREO MCS, GPS	2
	SI-LOK, GPS	1
	ELLIPSE & QUARTEX, GPS	2

Subtotal \$ 727,500

999.892	Shipping	NA	\$7,500	\$7,500
			Total	\$ 735,000

Terms and Conditions

Final purchase and terms of sale shall be exclusively governed by Globus' Software License and Sales Agreement.

Pricing valid through the Expiration Date stated above. This quotation sets forth the pricing offered by Globus but does not constitute a contract for sale. Final purchase and terms of sale shall be exclusively governed by Globus' Software License and Sales Agreement. Prices quoted are exclusive of all sales, use, excise, gross receipts, or other federal, state, or local taxes or other assessments as well as any export and import duties and associated fees, if applicable.