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HeartStitch Passes Critical Regulatory Audit in Kazakhstan

HeartStitch®, Inc. Announced That It Has Passed Its First Regulatory Audit Performed By The National Center for Expert Review of the Medical Products in Almaty, Kazakhstan

Astana, Kazakhstan—February 5, 2016—HeartStitch® announced that it has successfully passed its review and audit by the National Center for Expert Review of the Medical Products. Representatives from the NCER flew from Kazakhstan to the HeartStitch® facility in California to perform an extensive regulatory audit. This audit consisted of review of the company's manufacturing facilities, personnel training, procedures, and quality and regulatory systems.

Additionally the auditors reviewed the product technical files, design history files, CE approvals, and FDA clearances—as well as clinical data for the NobleStitch™ EL—as part of the HeartStitch® registration application for approval of the the NobleStitch™ EL for PFO closure and Cardiac suturing in the Republic of Kazakhstan.


Prof. Nobles explains clean room process

The two-day audit was supervised by Professor Anthony Nobles, Chairman and CEO of HeartStitch®—and Kazbek Aubakirov—Director of HeartStitch's ROK operations.

During the audit HeartStitch® staff provided extensive documentation for review, as well as performed product testing and manufacturing processes specifically for inspection by the auditors.


Prof. Nobles performs NobleStitch™ EL functional test

At the conclusion of the audit, the final review was presented. The auditors' preliminary review stated that there were no significant observations or warnings, and that they would recommend approval of the facilities as a certified medical device manufacturing facility. Following final review by the NCER, HeartStitch® has received its formal approval and certification of its California facility as a medical device manufacturer for the Republic of Kazakhstan.

"This audit was different than any previous audit we have undergone, although it covered all of the items we normally see with our European Notified Body and FDA inspections. It also required us to repeat initial

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product qualification testing so they could see the original testing during the audit. This was something that is not done in traditional audits, and we are proud to say that our extensive systems and repeatable processes performed perfectly, which led to this successful result," commented Edith Ramos, Director of Quality and Acting Director of Regulatory Affairs for HeartStitch's California operations.


Inspectors watching manufacture of NobleStitch™ EL

"This is an important step in getting approval for our products made in California, to be able to be registered here in Kazakhstan. After the successful audit we believe we will receive approval of the NobleStitch™ EL in the next few days. This is also an important step in setting up our Kazakhstan-based manufacturing facilities, where we will be using the same quality system and procedures, and which we expect to open in this upcoming month," stated Kazbek Aubakirov- Director of HeartStitch's ROK operations.

"I was very impressed by the auditors' level of expertise, and their knowledge of US and European standards. Their ability to review broad ranges of technologies with such efficiency would normally be difficult even in one's native language, however they were very detailed and professional in their approach. We are very proud of our relationship in Kazakhstan and this successful audit further strengthens that bond," said Professor Anthony Nobles, Chairman and CEO of HeartStitch™ and Professor of Biomedical Engineering at the West Sachsen University, Zwickau.


Inspectors perform final inspection of NobleStitch™ EL

About HeartStitch®

HeartStitch® Inc. was founded by Prof. Anthony Nobles with the intent of leveraging its technologies in the structural heart marketplace. HeartStitch® is focused on the innovative suture-based systems for remotely providing suture repair of structural heart defects and other vascular structures.

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The HeartStitch® TA and HeartStitch® MR are FDA cleared for vascular suturing in the United States. The NobleStitch™ EL is FDA cleared for vascular suturing in the United States and CE Marked for cardio-vascular suturing and PFO closure in the European Union and the Republic of Kazakhstan respectively.

HeartStitch® manufactures and markets the NobleStitch™ EL under and exclusive license.

HeartStitch® is a registered trademark of HeartStitch, Inc.

HeartStitch® TA for cardiac suturing and transapical access and closure
Covered by or for use under U.S. and international patents including one or more of U.S. Patent Nos. 5860990, 6117144, 6245079, 6551331, 6562052, 6733509, 7004952, 7090686, 7803167, 8197497, 8348962, 8469975, 8496676, and 8709020.

HeartStitch® MR for suturing an anatomical valve
Covered by or for use under U.S. and international patents including one or more of U.S. Patent Nos. 5860990, 6117144, 6245079, 6551331, 6562052, 6733509, 7004952, 7090686, 7803167, 8197497, 8348962, 8469975, 8496676, 8709020, and 8771296.

NobleStitch™ EL for PFO closure
Covered by or for use under U.S. and international patents including one or more of U.S. Patent Nos. 5860990, 6117144, 6245079, 6551331, 6562052, 6733509, 7004952, 7090686, 7803167, 8197497, 8197510, 8246636, 8348962, 8372089, 8469975, 8496676, 8709020, and 9131938.

For more on **HeartStitch®** visit www.HeartStitch.com

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