FOR IMMEDIATE RELEASE

HeartStitch, Inc. Passes Complex FDA Audit

HeartStitch, Inc. passes FDA audit after integrating the manufacturing and systems of the NobleStitch™ EL into full production in 2016.

Fountain Valley, California—Wednesday, March 9, 2016— HeartStitch® today announced that it has successfully passed its 2016 FDA audit just after integrating the full manufacturing systems and processes for building the NobleStitch™ EL. HeartStitch® recently entered into a distribution and manufacturing agreement with Nobles Medical Technologies II to produce and sell the NobleStitch™ EL. This presented a challenge in preparing for the 2016 FDA Audit. The Staff worked hard to integrate the product into its manufacturing in time for the audit.

Prof. Anthony Nobles, CEO of HeartStitch® commented, "It was a big task to completely integrate a new product into our systems just a few months before a major FDA audit. Our staff all worked tirelessly to complete the process—both to meet the product release dates and schedules—and to be ready for the FDA audit. I am very proud of the effort and the results our talented team demonstrated. We are committed to deliver the best products, built to the highest standards."

Ben Brosch, President of HeartStitch® commented, "HeartStitch® had been primarily a research and development company over the past several years and recently transitioned into full manufacturing mode. This audit is the test of that process, and the verification that we are meeting the FDA's requirements. We have and will continue to meet or exceed the standards we are held to as a medical device manufacturer."

Faye Dunn, Director of Regulatory affairs stated, "After recently joining HeartStitch® I was immediately impressed with the successful history Prof. Nobles has had with the FDA at all his companies over the years. I was also impressed with the team here at HeartStitch® and I believe its my responsibility to maintain this outstanding record."

About Transapical Access and Closure

Transapical Access and Closure is the technique of entering the left ventricle of the beating heart with an access device such as a cannula or sheath that allows the physician to access the chambers of the heart directly to perform procedures on the internal structures of the heart such as the valves, Left Atrial Appendage (LAA) and the septum. After completion of the procedure the access device is removed and the apical hole is closed using sutures. This technique allows for the use of larger devices and more direct control during the procedure as compared to the femoral or other remote vascular access which limits the size and increases the complexity of the devices used. Transapical Access and Closure can be performed in an open surgical setting, a limited thoracotomy which is a small incision between the ribs or percutaneously through a puncture in the intercostal space between the ribs.

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.

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

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

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