CryoLife Announces Resolution of FDA Warning Letter

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ATLANTA, April 27, 2015 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today that it has received a close-out letter from the United States Food and Drug Administration ("FDA") verifying that the Company has successfully implemented corrective actions put in place following the warning letter it received from the FDA in January 2013.

The close-out letter follows a re-inspection in March 2015 by the FDA at CryoLife's manufacturing facility and headquarters in Kennesaw, GA. The receipt of the close-out letter confirms that all items in the warning letter were closed, with the FDA determining that the Company's remediation activities are effective and its quality management system is in substantial compliance. No FDA 483 observations were issued as part of the follow-up inspection.

Pat Mackin, Chairman, President, and Chief Executive Officer, said, "Resolving the FDA warning letter was my top priority when I joined the Company. I am pleased that we passed the recent FDA re-inspection with no 483 observations and that the FDA has lifted our warning letter. The CryoLife team did a great job responding to the FDA's concerns, and we are committed to the continued enhancement of our quality systems and delivery of the highest quality products to patients."

About CryoLife
Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of implantable living tissues and medical devices used in cardiac and vascular surgical procedures. CryoLife markets and sells products in more than 75 countries worldwide. For additional information about CryoLife, visit our website, www.cryolife.com.

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