



Endologix Provides Update on Previously Announced Voluntary Nellix System Recall

January 22, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Jan. 22, 2019-- Endologix® Inc. (Nasdaq: ELGX), a developer and marketer of innovative treatments for aortic disorders, announced today that the EC Certificate of Conformity (CE Mark) for the Nellix EndoVascular Aneurysm Sealing System (Nellix System) has been suspended by its Notified Body, GMED, following a voluntary recall and Field Safety Notification (FSN) issued by Endologix on January 4, 2019.

"The notification from GMED is a regulatory action and is not in response to any new information beyond our recent FSN," said Dr. Matt Thompson, Chief Medical Officer of Endologix. "This action is consistent with our previously articulated plans for the Nellix System and does not affect other Endologix products. We remain steadfast in our commitment to patient safety and believe in the transformational potential of Nellix."

Earlier this month, Endologix announced that the Nellix System will for the foreseeable future be made available only for use at approved centers in a clinical investigation setting, with all cases pre-screened by a physician panel and supported by Endologix to ensure use in accordance with the current indications and optimal clinical outcomes.

Suspension of the CE Mark means that Endologix may not affix the CE Mark and sell the Nellix System in the European Union during the term of the suspension.

Endologix does not expect this action to impact its previously communicated financial guidance for 2019.

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The Company's focus is in endovascular stent grafts for the treatment of abdominal aortic aneurysms (AAA). AAA is a weakening of the wall of the aorta, the largest artery in the body, resulting in a balloon-like enlargement. Once an AAA develops, it continues to enlarge and, if left untreated, becomes increasingly susceptible to rupture. The overall patient mortality rate for ruptured AAA is approximately 80%, making it a leading cause of death in the U.S. For more information, visit www.endologix.com.

Cautions Regarding Forward-Looking Statements

Except for historical information contained herein, this press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "could," "may," "will," "believe," "estimate," "forecast," "goal," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements used in this press release include: limited availability of the Nellix System in the foreseeable future at approved centers in a clinical investigation setting to ensure use in accordance with the current indications and optimal clinical outcomes; effect of the CE Mark suspension, and; the expectation that the CE Mark suspension will not impact Endologix's previously communicated 2019 financial guidance, the accuracy of which are necessarily subject to risks and uncertainties that may cause Endologix's actual results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ materially and adversely from anticipated results include, continued market acceptance, endorsement and use of Endologix's products, the success of clinical trials relating to Endologix's Nellix System and other products, product research and development efforts, uncertainty in the process of obtaining and maintaining regulatory approval for Endologix's products, Endologix's ability to continue to access the capital markets on terms acceptable to it or at all, Endologix's ability to remain in compliance with its obligations to its creditors and other counterparties, Endologix's ability to protect its intellectual property rights and proprietary technologies, and other economic, business, competitive and regulatory factors. The forward-looking statements contained in this press release speak only as of the date of this press release. Endologix undertakes no obligation to update any forward-looking statements contained in this press release to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to Endologix's filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2017, and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018, June 30, 2018, and September 30, 2018 for more detailed information regarding these risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied.

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