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Endologix Announces CE Mark Approval for the Nellix® EndoVascular Aneurysm Sealing System with the Refined Indications for Use

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix, Inc. (NASDAQ: ELGX), a developer and marketer of innovative treatments for aortic disorders, today announced the CE Mark approval for its Nellix® EndoVascular Aneurysm Sealing System ("Nellix") with the refined Indications for Use (IFU). Nellix is being studied in the U.S. under an Investigational Device Exemption (IDE).

Following a thorough review of supporting clinical data, the Company's notified body, together with an independent clinical reviewer, has determined that Nellix, with the refined IFU, meets the applicable safety and clinical performance requirements. As a result of these evaluations, the notified body has granted a CE Mark for Nellix with the refined IFU.

"We are very pleased with the clinical outcomes generated by the Nellix EndoVascular Aneurysm Sealing System utilizing the refined IFU," commented John McDermott, Endologix's Chief Executive Officer. "The Nellix CE Mark with the refined IFU provides patients and physicians in Europe with continued access to the clinical benefits of complete aneurysm sealing, including low rates of endoleaks and all-cause mortality."[1]

About Endologix

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The Company's focus is 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 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, but are not limited to, statements regarding continued access to, and benefits of, certain of Endologix's existing products and potential future products, 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 uncertainty in the process of obtaining regulatory approvals for Endologix's products, continued market acceptance, endorsement and use of Endologix's products, the success of Endologix's product development and quality assurance efforts, the success of clinical trials relating to Endologix's products, product research and development efforts, risks associated with obtaining third party payer reimbursement, Endologix's ability to compete on price and quality, risks associated with international operations including currency exchange rate fluctuations, Endologix's ability to protect its intellectual property rights and proprietary technologies, and other economic, business, competitive and regulatory factors. Undue reliance should not be placed upon the forward-looking statements contained in this press release, which 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 filings on Form 10-K and Form 10-Q, 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.

[1] Carpenter, J.P. (2017, June). Nellix System for Endovascular Aneurysm Sealing: Effect of IFU Refinements on Outcomes from the EVAS FORWARD IDE. Presented at the 2017 Vascular Annual Meeting, San Diego, CA.

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