Press release |

Stroke2prevent receives FDA 510(k) clearance for A-View®

Zwolle, The Netherlands – 29 May 2017, Stroke2prevent BV, an innovative Dutch medical device company, announced that it has received FDA 510(k) clearance for A-View®, a unique medical device, used in cardiac interventions. A-View® balloon catheter visualizes the aortic arch with Transesophageal Echocardiography (TEE). "Receiving US FDA 510(k) clearance for A-View® is a major milestone to make this technology available to clinicians and contribute to improved outcomes for cardiac patients" said Maarten Nibbelke, CEO of Stroke2prevent.

About A-View: A-View® is intended to resolve the so called blind-spot of TEE, caused by interposition of the trachea. A-View® is used to provide imaging of the entire aortic arch and has demonstrated to detect atherosclerosis, diagnose aortic diseases and to monitor vascular flow. The additional information obtained by A-View® supports surgeons to ensure the best patient outcomes.
A-View® is currently marketed in Europe and will become available in the US soon, pending arrangements for a proper distribution and clinical support channel.

About Stroke2prevent: Stroke2prevent BV develops, manufactures and distributes medical devices. Its products and services are focused on cardiac surgery, interventional cardiology and TEE screening. The company was founded in 2011 and is headquartered in Zwolle, the Netherlands.

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