



# CVR Medical Completes FDA Submission for Highly Anticipated CSS Device

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DENVER, NORTH CAROLINA, USA, January 7, 2019 /EINPresswire.com/ -- CVR Medical Corp. (CVM.V) (TSXV: CVM) (OTCQB: CRRVF) ("CVR Medical") a Canadian listed and US based healthcare company in the medical device sector announces it has completed a Food and Drug Administration De Novo Submission for their "Carotid Stenotic Scan (CSS)" device. A De Novo Submission allows for a company to receive a "not substantially equivalent" risk-based evaluation for any legally marketed device for which there is no prior, comparable classification. As a novel device that uses patented sound wave analysis technology to detect and measure carotid arterial stenosis, the CSS fits within the criteria of this FDA filing. Due to US government shutdown, the submission will be reviewed by the FDA upon resumption of government activity.

Peter Bakema, Chairman and CEO of CVR Medical, states, "Today's FDA submission marks the culmination of CVR's many years of product development, design, trials and organizational preparation. It is an important and necessary step for any new device entering the market, and one that is worth the wait to be executed correctly. I am proud of our staff and partners around the world for their contributions in getting us to this stage, and look forward to keeping shareholders, as well as the greater public, up to date on the process as it moves ahead. We at CVR will continue to work during the submission phase to ensure that upon its success, we are ready to maintain momentum with the market release of the CSS."

## About CVR Medical

CVR Medical Corp. is a healthcare company that operates in the medical device industry focused on the commercialization of its disruptive, proprietary Carotid Stenotic Scan (CSS). The CSS device is a diagnostic tool that encompasses subsonic, infrasonic, and low frequency sound wave analysis technology. The CSS is a patented device designed to detect and measure carotid arterial stenosis. CVR is currently in pivotal clinical trials in preparation for its planned submission to the FDA. CVR is led by an experienced and proven team of professionals with extensive healthcare, medical device, international expansion, regulatory and sales experience. CVR Medical trades on the TSX Venture Exchange under the symbol CVM. Additional information regarding the Company can be found in our recent filings with the SEDAR as well as the information maintained on our website at [www.cvrmed.com](http://www.cvrmed.com)

ON BEHALF OF THE BOARD:  
(signed) "Peter Bakema"  
CEO, President & Director

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This press release contains forward-looking information that involves various risks and uncertainties regarding future events related to the Joint Venture. Such statements are subject to risks and uncertainties that may cause actual results, performance or developments to differ materially from those contained in the statements and are not guarantees of future performance of the Company. No assurance can be given that any of the events anticipated by the forward-looking statements will occur or, if they do occur, what benefits the Company will obtain from them. These forward-looking statements reflect management's current views and are based on certain expectations, estimates and assumptions which may prove to be incorrect. A number of risks and uncertainties could cause our actual results to differ materially from those expressed or implied by the forward-looking statements, including: (1) a downturn in general economic conditions in North America and internationally, (2) the inherent uncertainties and speculative nature associated with commercialization of technology and the practice of medicine, (3) a change in health regulations, (4) any number of events or causes which may delay or cease commercialization and development of the Joint Venture, (5) the risk that the Company or the Joint Venture does not execute its business plan, (6) inability to retain key employees, (7) inability to finance operations and growth, and (8) other factors beyond the Company's control. These forward-looking statements are made as of the date of this news release and, except as required by law, the Company assumes no obligation to update these forward-looking statements, or to update the reasons why actual results differed from those projected in the forward-looking statements.

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