



FOR: CARDIOCOMM SOLUTIONS, INC.
TSX VENTURE SYMBOL: EKG

December 31, 2018

CARDIOCOMM SOLUTIONS' HEARTCHECK™ CARDIBEAT FDA 510(K) REVIEW EXTENDED

FDA Removes Additional Clinical Testing Requirements for the HeartCheck™ CardiBeat

TORONTO, ONTARIO - CardioComm Solutions, Inc. (TSX VENTURE:EKG) ("**CardioComm**" or the "**Company**"), a leading global provider of consumer heart monitoring and electrocardiogram ("**ECG**") acquisition and management software solutions, confirms the USA Food and Drug Administration ("**FDA**") has reduced the scope of their request for additional information for the Company's premarket notification 510(k), Class II medical device clearance application for the HeartCheck™ CardiBeat and GEMS™ Mobile Application.

CardioComm submitted its most recent 510(k) application to the FDA for Class II Medical device clearance on the HeartCheck™ CardiBeat as previously reported. The Company was then requested by the FDA to provide additional data that included clinical evaluations to confirm the device's ability to record ECGs equivalent to those using conventional ECG electrode patches and ECG cables.

Subsequent to receiving the Company's reply with additional data, the FDA provided guidance on two primary items. These were:

- 1) the Company no longer was required to support the request for extensive ECG electrode testing data; and,
- 2) additional data was requested related to Bluetooth wireless coexistence testing.

In compliance to the FDA's directive, the Company has submitted a letter of revocation of their supplementary information submission which was accepted by the FDA on December 26, 2018. The Company will provide the FDA a restatement of their response for additional information to the FDA by January 23, 2019 without clinical ECG testing data and with the requested wireless coexistence data. The FDA will have 31 days to complete the 510(k) review following receipt of CardioComm's restated submission.

The Company will provide updates on this and future 510(k) applications. To learn more about CardioComm's products and for further updates regarding HeartCheck™ ECG device integrations please visit the Company's websites at www.cardiocomm solutions.com and www.theheartcheck.com.

About CardioComm Solutions

CardioComm Solutions' patented and proprietary technology is used in products for recording, viewing, analyzing and storing electrocardiograms for diagnosis and management of cardiac patients. Products are sold worldwide through a combination of an external distribution network and a North American-based sales team. CardioComm Solutions has earned the ISO 13485:2016 certification, is HIPAA compliant and holds clearances from the European Union (CE Mark), the USA (FDA) and Canada (Health Canada).

FOR FURTHER INFORMATION PLEASE CONTACT:

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Forward-looking statements

This release may contain certain forward-looking statements and forward-looking information with respect to the financial condition, results of operations and business of CardioComm Solutions and certain of the plans and objectives of CardioComm Solutions with respect to these items. Such statements and information reflect management's current beliefs and are based on information currently available to management. By their nature, forward-looking statements and forward-looking information involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements and forward-looking information.



In evaluating these statements, readers should not place undue reliance on forward-looking statements and forward-looking information. The Company does not assume any obligation to update the forward-looking statements and forward-looking information contained in this release other than as required by applicable laws, including without limitation, Section 5.8(2) of National Instrument 51-102 (*Continuous Disclosure Obligations*).

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