



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

**August 2, 2018**

**CARDIOCOMM SOLUTIONS FDA 510K APPLICATION FOR NEWEST HEARTCHECK™ ECG DEVICE  
AND SMART PHONE APP ENTERS THE NEXT STAGE OF REVIEW**

Company moves into next phase of approval review intended for market release of HeartCheck™ CardiBeat  
and GEMS™ Mobile Application

**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, has received a request for additional information from the USA Food and Drug Administration ("**FDA**") following the Company's filing of its premarket notification 510(k), Class II medical device clearance application for the HeartCheck™ CardiBeat and GEMS™ Mobile application.

While CardioComm will have 180 days to provide a reply to the FDA examiner, the Company intends to respond within a much shorter time period of 90 days. The requests for additional information were expected as a result of recent changes that have been made to the medical device clearance review process, especially with respect to personal information protection and electronic data access (PIPEDA) and data security standards.

The HeartCheck™ CardiBeat will also be branded as the HeartCheck™ Beat. The Bluetooth enabled and rechargeable handheld device will allow for a medical grade ECG recording to be taken simply by holding the device in both hands (a Lead I ECG recording), or for a Lead II ECG to be recorded when held in the right hand and against the left side of the chest. Lead II measurements are more accurate and clinically preferred by physicians for recording and diagnosing arrhythmias such as atrial fibrillation, and this represents a significant diagnostic advantage over other currently available devices.

The FDA premarket notification 510(k) application included CardioComm's iOS/Android compatible GEMS™ Mobile App. GEMS™ Mobile is based directly on the Company's Global ECG Management Solutions (GEMS™) software. As indicated in the Company's May 22, 2018 press release, GEMS™ Mobile will have compatibility with a number of different wireless ECG recording devices, including the option to support wireless 12 lead devices. Future 510K applications will be registered as the company continues to identify and integrate new ECG devices compatible with the same GEMS™ Mobile application contained in the current 510(k) filing.

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.com](http://www.cardiocomm.com) and [www.theheartcheck.com](http://www.theheartcheck.com). See the Company's May 22, 2018 press release for further information regarding the initial FDA filing.

**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 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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