



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

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## **CARDIOCOMM SOLUTIONS RECEIVES FDA CLEARANCE FOR PRESCRIPTION USE OF THE HEARTCHECK™ ECG PEN**

**FDA Clearance for the HeartCheck™ ECG PEN Now Extended to Prescription Use: The continuum of care is complete with both physician prescribed and over the counter (OTC) FDA clearances for sales and marketing of the PEN in the USA**

**Toronto, Canada** – CardioComm Solutions, Inc. (TSX-V:EKG) (“CardioComm Solutions” or the “Company”), a global medical provider of ECG acquisition and management software solutions, today announced it has received clearance from the Food and Drug Administration (FDA) for “prescription-use” sales and marketing of their hand-held heart rhythm monitor known as the HeartCheck™ ECG PEN.

This is the second FDA clearance within six months for the Company, and specifically for the handheld HeartCheck™ ECG PEN™ highlighting the ability for the PEN to now be prescribed and used by physicians in arrhythmia screening/monitoring and stroke and sudden death prevention efforts. The FDA clearance also recognizes and includes CardioComm Solutions’ GEMS™ (Global ECG Management System) Home software, which in this version, enables the actual ECG recording to be viewed on a personal computer and then to be uploaded to either the CardioComm Solutions’ Smart Monitoring medical call service or any GEMS™ enabled telemedicine group for review by a physician.

“Consumers and patients can now all have access to the HeartCheck™ ECG PEN device and may involve their physician upfront or as needed. Whether purchased over-the-counter as a consumer product or provided in the pharmacy through insured reimbursement for a prescribed ECG monitor, monitoring of your heart health is now be available to anyone, especially to those who may be at risk for stroke or sudden cardiac death” said Etienne Grima, Chief Executive Officer of CardioComm Solutions. “This second FDA clearance closes the loop on access to the general population to perform ECG screening and monitoring under a system that ensures physician or health care professional oversight. In the available OTC and prescription versions, this device ensures a continuum of care regardless of one’s ability to access a cardiologist or qualified health care professional.”

“This approval exceeded our expectations on timelines for clearance of the HeartCheck™ PEN device and we can now fully move into the sales launch of the PEN in multiple medical applications across the USA and the rest of the world. Requests for distribution rights of the HeartCheck™ PEN have been received from potential distributors in over 50 countries and we are working to qualify and prioritize them as we ramp up production.” said Simi Grosman, member of the CardioComm Solutions Board of Directors.

“The medical applicability of this prescription-use clearance in addition to the OTC approval cannot be overstated: as a cardiologist this is the first instance that I am aware of where a device is capable of screening for an arrhythmia that may be the single most important cause of stroke or sudden death, examples of which we as a medical community have seen in our patients or even in premier athletes. The fact that the device is capable of detecting the heart rhythm disorders is powered by the GEMS™ Smart Monitoring Service and speaks to the intended use of the HeartCheck PEN as an ECG and/or heart rate (ECG Locked) recording device capable of providing diagnostic quality readings to a physician for use to make individualized prognostic recommendations to the informed individuals and patients. CardioComm Solutions is a medical software engineering company with over fifteen years of FDA clearances and I can see no better representation for enabling true, remote, physician engaged cardiac arrhythmia monitoring. People interested in taking a proactive role in monitoring their cardiac health now have options with the HeartCheck™ PEN” said Dr. Anatoly Langer.

### **About CardioComm Solutions**

CardioComm Solutions’ patented and proprietary technology is used in products for recording, viewing, analyzing and storing electrocardiograms (ECGs) 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. The Company has earned the ISO 13485 certification, is HPB approved, HIPAA compliant, and has received FDA market clearance for its software devices. CardioComm Solutions, Inc. is headquartered in Toronto, Canada, with offices in Victoria, B.C.

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**Forward-looking statements**

This release may contain certain forward-looking statements 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. By their nature, forward-looking statements 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.

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