

CardioComm gets FDA nod for smartphone app, new ECG device

The longtime player in the home ECG space may be shoring up to compete with the likes of Apple.

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Toronto-based CardioComm, a longtime player in the handheld personal ECG space will finally make data available on consumers' smartphones with a new 510(k) clearance for its GEMS Mobile smartphone app, which works on both iOS and Android devices. The company also received clearance for a new ECG device called HeartCheck CardiBeat.

Notably, these are over the counter clearances, allowing the app and device to be sold directly to consumers.

What's the impact

The company described the app in a press release as a "slimmed down version" of its Global ECG Monitoring System (hence, GEMS) for hospital use. The app will integrate not only with CardioComm devices, but with ECG devices from other manufacturers as well.

In addition to Bluetooth connectivity, CardiBeat differs from previous CardioComm devices in that it can be used in two different ways.

"The Bluetooth enabled and rechargeable CardiBeat allows a medical grade ECG recording to be taken by holding the device in both hands or by holding the device in the right hand and against the left side of the chest," the company explained. "This second option is more accurate for diagnosing arrhythmias such as atrial fibrillation and atrial flutter. This represents a significant diagnostic advantage over other devices currently on the market."

As for the app, it allows for both post-event and continuous ECG monitoring. Via an additional paid service, users can also have their ECGs interpreted by experts. The company expects the app to hit app stores in March. It will be free with the purchase of a HeartCheck device.

What's the trend

While Apple's bombastic entry brought a lot of new attention to the world of consumer ECGs, a handful of companies have been working on, and offering them, for years. CardioComm is one of those early pioneers, **receiving FDA clearance for its HeartCheck ECG PEN** way back in January 2012.

The company has dabbled in smartphone connectivity over the years, **using consumer smartphones to help transmit data** for remote patient monitoring. It also **announced a smartphone-connected wearable ECG back in 2016**, but that device never came to market.

With the new consumer awareness of the space, consumers interested in ECG but turned off by Apple's price point or lack of realtime telemetry may be looking to legacy players like CardioComm **and AliveCor**, so moving into smartphone connectivity right now makes a lot of sense for CardioComm.