



FDA clearance for QardioCore

Qardio Announces FDA Clearance for QardioCore, a self-fit continuous ambulatory ECG to view and annotate ECG

Cloud-Based ECG Service Provides Continuous Monitoring and Full Disclosure Reports for Clinical Diagnostics

SAN FRANCISCO, Calif. March 4, 2021 – **Qardio, Inc.** announced today that the U.S. Food and Drug Administration (FDA) has granted the company 510k clearance for its QardioCore ambulatory ECG device. QardioCore will initially be marketed for holter monitoring applications, for use with QardioMD, Qardio’s cloud-based remote patient monitoring solution.

QardioCore extends Qardio’s remote patient monitoring platform from primary care and hypertension monitoring to acute care and cardiology, in a single, intuitive platform.

QardioCore requires no special skin preparation, gels, adhesives, or patches. It can easily be self-fit, removed, and re-fit by the patient. Ideal for remote deployment, QardioCore does not require an in-clinic fitting. Qardio intends to launch the service in the U.S. in mid-2021.

Qardio co-founder Rosario Iannella commented “Our goal for QardioCore has always been to create a better experience for patients and care providers. For patients, there is much less inconvenience in comparison to traditional monitors. For providers, patient usability leads to compliance – so QardioCore can deliver high diagnostic yields by design.”

Qardio CEO Mark Prince added “Our initial ECG service has been designed for remote deployment and works right out of the box. Patients will find that QardioCore is as easy to use as a common heart rate monitor, but with the power of an ECG, to relay rhythms to a full disclosure presentation in QardioMD. QardioCore enables providers to receive telemetry in as little as 24 hours, which can dramatically accelerate time to diagnosis.”

QardioCore is intended to capture continuous ECG rhythms. QardioCore + QardioMD display full disclosure ECG reports and may be used under the care of a physician to identify arrhythmias. QardioMD is easily integrated with EHRs and other digital health platforms, and reports may be easily exported in a single click. A cloud-based service by design, QardioCore + QardioMD perfectly complements other telehealth services.

QardioCore is intended for use by healthcare professionals, when treating patients who may be asymptomatic or with known or suspected heart conditions . The device has not been tested for and it is not intended for paediatric use. With secure storage in the cloud, clinicians have the ability to access patient data securely, anytime, anywhere. These services are expected to be available in U.S. in the second half of 2021.

More information is available at www.qardiomd.com