

Category

Best Medical Technology

Drug / Device Name

PCA 500

Compound/ Tech Name

Baby XpressECG

Trade Name

Baby XpressECG

Date of Approval

2022-09-26

Indications

The QT ECG System is intended to acquire, record and process an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology to a cell-phone or mobile device, then to a remote location. The QT ECG System is indicated for use on infants, children and adults. It is designed to be operated by adults in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), to record and transmit a 12-lead ECG and rhythm strip in near real-time to enable review at a physician's office, hospital or other medical receiving centers.

Therapeutic Categories

Cardiovascular

Background information and need for drug/device

Congenital long QT syndrome (LQTS) occurs 1 in every 2000 newborns. If untreated, LQTS can cause arrhythmia and sudden death.

About 15% SIDS cases are due to LQTS, or over 300 infants in the US die every year from LQTS and are thought to be SIDS. If diagnosed early, LQTS can be well managed with medical therapy and an implantable defibrillator. However, ECG screening of newborns was difficult and not cost effective in the past. We created the first ECG device for this purpose, called PCA 500, which enable to parents to do a full medical standard 12-lead ECG on their babies in their own homes.

History of the development of the drug/device

The development of PCA 500 was initially funded by NIH. We developed the world's smallest and most user-friendly ECG for use in pediatric patients. The device was tested in a randomized controlled trial of

2582 newborns for screening for LQTS. The results showed that most parents (94%) were able to complete an ECG test with no need for training. PCA 500 was cleared by the FDA via 510(k) in 2018 for use in adults. In September 2022, we obtained FDA clearance for use of PCA 500 in newborns, infants and children. We created a home ECG testing service called Baby Xpress ECG for parents to do the baby's ECG screening at home.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

PCA 500 is the only medical standard 12-lead ECG cleared by the FDA for professional use and laypeople use. It has been used in hospitals, clinics, clinical trials, schools, prisons and commercial flights. The mail order home ECG testing service is the only ECG in the world that can be performed by patients at home and ECGs are available for physician review instantly. PCA 500 makes the most useful test for the heart-- 12-lead ECG, widely accessible and affordable to all patients. The Baby Xpress ECG will be the only service in the world for screening newborns for LQTS, arrhythmias, heart blocks and congenital heart disease. It has the potential for saving thousands of lives in the US every year.

Please provide appropriate references (ie Pubmed links)

Comparison of electrocardiogram quality and clinical interpretations using prepositioned ECG electrodes and conventional individual electrodes. J Electrocardiol . 2020 Mar-Apr;59:126-133. PMID: 32062382

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Home use of a compact, 12-lead ECG recording system for newborns. J Electrocardiol . 2019 Mar-Apr;53:89-94. PMID: 30716528

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Resting 12-lead ECG tests performed by patients at home amid the COVID-19 pandemic - Results from the first 1000 patients. J Electrocardiol. 2022 Jul-Aug;73:108-112. PMID: 35803062

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