National Cardiac, Inc.
% Don Canal
Consultant
510k Medical, Inc.
1200 Post Oak Trail
Southlake, Texas 76092

Re: K182532
Trade/Device Name: Liba3 System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: DSI, MHX
Dated: April 16, 2019
Received: April 18, 2019

Dear Don Canal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the senclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Matthew Hillebrenner
Director (Acting)
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182532

Device Name

Liba3™ System

Indications for Use *(Describe)*

The Liba3™ System is an ambulatory cardiac monitoring system prescribed by a physician or other qualified healthcare professional for out-patient individuals with known non-lethal arrhythmias such as:

- Atrial Fibrillation
- Bradycardia
- Tachycardia
- Pause

It continuously monitors, records, and stores electrocardiographic (ECG) data. If equipped with a transmitter, the Liba3™ will also periodically transmit ECG Cardiac Event to a remote computer server. Both recorded and transmitted ECG data are available to HealthCare Providers for analysis and reporting.

Liba3™ is intended to be used with adult patients 22 years and older, but not designed for pediatric patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

A. Sponsor

National Cardiac, Inc.
221 W. Crest Street, Suite 205
Escondido, CA 92025

Contact Person: Don Canal (Consultant)
Contact Phone: 972-955-7644
Contact Email Address: don@510kmedical.com

Date Prepared: September 9, 2018

B. Device Name

Trade Name: Liba3 System

Classification Regulation:	21 CFR 870.1025
Regulation Name:	Arrythmia Detector and Alarm (Including ST-Segment Measurement)
Regulatory Class:	Class II, Special Controls
Product Code:	MHX, DSI

C. Predicate/ Reference Devices

The Subject Device is a modification to the Context International Technologies, Inc. NowCardio™ System, cleared under K162956.

D. Intended Use / Indications for Use

The Liba3™ System is an ambulatory cardiac monitoring system prescribed by a physician or other qualified healthcare professional for out-patient individuals with known non-lethal arrhythmias such as:
• Atrial Fibrillation
• Bradycardia
• Tachycardia
• Pause
It continuously monitors, records, and stores electrocardiographic (ECG) data. If equipped with a transmitter, the Liba3™ will also periodically transmit ECG Cardiac Event to a remote computer server. Both recorded and transmitted ECG

data are available to HealthCare Providers for analysis and reporting. Liba3™ is intended to be used with adult patients 22 years and older, but not designed for pediatric patients.

E. Device Description

The Liba3™ System is a wearable, wireless arrhythmia detection system that provides continuous cardiac monitoring functionality for an extended period of time. Each Sensor can be worn for up to 7.5 days. If the prescribed monitoring period exceeds 7.5 days, National Cardiac, Inc. will provide additional sensors. For a 30-day monitoring period, the patient would be required to use four (4) Sensor components. The Liba3 System is prescribed by healthcare providers to monitor, record, and report on a patient's electrocardiographic (ECG) data.

The Liba3 system consists of: (1) a wearable electronic component that collects and monitors a patient's single lead ECG data referred to as a Liba3™ Sensor; (2) an optional transmitting device, referred to as the Liba3 transmitting device, that is used for ECG data transmission while the patient is wearing the sensor and for transmission of patient triggered events; and (3) a Remote Data Management System (RDMS) which is a remote server with software that will allow qualified healthcare providers to receive, analyze, interpret, and report on the results of the ECG test.

F. Technological Characteristics

The following table contains a comparison of characteristics and specifications for the Subject Device and the predicate devices that are cleared under the same regulation number for the same indications for use.

Comparison Characteristic	Liba3 System (Subject Device)	Previously Cleared Device, NowCardio System (K162956)
Indications for use	The Liba3™ System is an ambulatory cardiac monitoring system prescribed by a physician or other qualified healthcare professional for out-patient individuals with known non-lethal arrhythmias such as: • Atrial Fibrillation • Bradycardia • Tachycardia • Pause	The NowCardio System is an ambulatory cardiac monitoring system prescribed by a physician or other qualified healthcare professional for out-patient individuals with known non-lethal arrhythmias such as: • Atrial Fibrillation • Bradycardia • Tachycardia • Pause It continuously monitors,

Comparison Characteristic	Liba3 System (Subject Device)	Previously Cleared Device, NowCardio System (K162956)
	It continuously monitors, records, and stores electrocardiographic (ECG) data. If equipped with a transmitter, the Liba3™ will also periodically transmit ECG Cardiac Event to a remote computer server. Both recorded and transmitted ECG data are available to HealthCare Providers for analysis and reporting. Liba3™ is intended to be used with adult patients 22 years and older, but not designed for pediatric patients.	records, and stores electrocardiographic (ECG) data. If equipped with a transmitter, the NowCardio will also periodically transmit ECG Cardiac Event to a remote computer server. Both recorded and transmitted ECG data are available to HealthCare Providers for analysis and reporting. NowCardio is intended to be used with adult patients 22 years and older, but not designed for pediatric patients.
FDA classification	Class II	Class II
Product Code/classification /common name	21 CFR 870.1025 Patient Physiological monitor (with Arrythmia detection) Arrythmia Detection and Alarm	21 CFR 870.1025 Patient Physiological monitor (with Arrythmia detection) Arrythmia Detection and Alarm
User event trigger	Yes	Yes
Environment of use	Home Use, Physician practices, clinics, research institutions	Home Use, Physician practices, clinics, research institutions
Prescription use	Yes	Yes
Physician access to patient physiological and event information	Yes	Yes
Arrythmia detection algorithm	Proprietary / Server side	Proprietary / Server side
Safety standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2

Comparison Characteristic	Liba3 System (Subject Device)	Previously Cleared Device, NowCardio System (K162956)
	IEC 60601-1-11 IEC 60601-2-47 IEC 62366	IEC 60601-1-11 IEC 60601-2-47 IEC 62366
Intended use patient population	Liba3 System is intended for use by individuals who are at risk of having cardiac disease and have intermittent symptoms indicative of cardiac disease. Adults 22 years or older.	NowCardio System is intended for use by individuals who are at risk of having cardiac disease and have intermittent symptoms indicative of cardiac disease. Adults 22 years or older
Preliminary data processing	Certified Technician, Remote Monitoring Data Center	Certified Technician, Remote Monitoring Data Center
Placement of sensor	Precordium	Precordium
Type of electrode/patch	Custom cutaneous electrodes integral with Liba3 Sensor.	Custom cutaneous electrodes for use with NowCardio Sensor.
Conductive gel	Hydrogel	Hydrogel
Sterility	Not Sterile	Not Sterile
Patient contact materials	Hydro Gel electrode. Electrodes have a pressure sensitive adhesive that enables the electrodes to be applied to the patient's skin.	Hydro Gel electrode. Electrodes have a pressure sensitive adhesive that enables the electrodes to be applied to the patient's skin.
Interface connection for data transmission	Bluetooth Low Energy (BLE)	Bluetooth or USB
Battery	Non-rechargeable coin cell. (disposable sensor) 7.5 day battery life	Rechargeable 48 hour battery life for sensor, transmitter 24 hour
Water resistant	Yes IP64	Yes IP24
Electrode shelf life	6 months	1 year
Dimensions	35mm width X 88mm length X 7mm height	54.6 mm width x 75.3mm x 11.9mm height
Associated	Sensor, Wireless	Sensor, wireless transmitter,

Comparison Characteristic	Liba3 System (Subject Device)	Previously Cleared Device, NowCardio System (K162956)
Components	transmitter, ECG Analysis SW	battery charger, ECG analysis SW
Software features	Software will be provided to allow Physicians and Cardiology Technologist's to receive, analyze, interpret, and report on the results of the ECG test	Software will be provided to allow Physicians and Cardiology Technologist's to receive, analyze, interpret, and report on the results of the ECG test
Hardware features	Disposable sensor module with integral adhesive electrodes, accelerometer to record patient triggered events, LED indicator	Sensor module, adhesive electrodes, Wireless transmitter, battery charger, charging cradle, Trigger alarm, LED indicator
Data Transmission methods	Bluetooth LE and cellular direct wired connection (for depot use only)	Bluetooth and cellular
Data storage capacity – sensor	7.5 days	32 days
Heart rate measurement range	10-250 Beats/min	10-250 Beats/min
ECG sampling rate	250Hz	250 Hz
A/D resolution	24 bit	12 bit
Visual indicator LEDs	Yes	Yes
Auditory indicators	No	Yes
Patient symptom trigger	Accelerometer/Double tap	Push button

G. Non-Clinical Performance Data

National Cardiac, Inc. has declared conformance to their design controls and has conducted the appropriate risk management activities to ensure that there are no

new issues of safety and effectiveness associated with the Subject Device when compared to the predicate device. Complete design verification activities which included verification of all design input requirements and ECG Analysis performance vs. recognized Databases, ECG analysis software validation, Sensor firmware verification, data integrity/cyber security, and testing was also completed to demonstrate compliance with FDA recognized industry standards as described in below.

H. Compliance with Standards

The Subject Device complies with the following standards:

- FDA Recognition Number 3-52, AAMI/ANSI EC-12:2000/(R)2012 Disposable ECG electrodes.
- FDA Recognition Number 3-127, ANSI AAMI IEC 60601-2-47:2012 (Second Edition) Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- FDA Recognition Number 2-245, ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- FDA Recognition Number 2-174, ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- FDA Recognition Number 19-4, ANSI AAMI ES60601-1:2005 (Third Edition)+CORR. 1:2006 + CORR. 2:2007+A1:2012 (or IEC 60601-1:2012 reprint) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- FDA Recognition Number 19-8, IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- FDA Recognition Number 19-14, ANSI AAMI IEC 60601-1-11:2015 (second Edition) General Requirements for basic Safety and essential performance-collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- FDA Recognition Number 5-40, ISO14971:2007/(R)2010 medical devices – Application of Risk Management to Medical Devices.
- FDA Recognition number 13-79, IEC 62304 Edition 1.1 2015-06 Medical Device Software – Software Life Cycle Processes
- ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

I. Substantial Equivalence

The National Cardiac Liba3 System has the same intended use/indications for use, and the same technological characteristics and principles of operation. There are minor technological/design differences that do not raise any new issues of safety or effectiveness. Based on the test results, compliance with FDA recognized industry standards, and the analysis provided in this Notice, National Cardiac, Inc. concludes that the Subject Device is substantially equivalent to the NowCardio predicate device cleared under K162956.