November 8, 2024

Fourth Frontier Technologies Pvt Ltd
Manav Bhushan
CEO
2nd and 3rd Floor, No. 794, 12th Main, 1st Cross, HAL,
2nd Stage, Indiranagar
Bengaluru, Karnataka 560038
India

Re: K240794
Trade/Device Name: Frontier X Plus
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MLO, DXH, DPS
Dated: November 7, 2024
Received: November 7, 2024

Dear Manav Bhushan:

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 enclosure) 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240794

Device Name
Frontier X Plus

Indications for Use *(Describe)*
The Frontier X Plus device is an ambulatory monitoring device intended to record, store, and transfer single-channel (ECG) rhythms for monitoring and evaluation. The Frontier X Plus system also displays ECG waveforms and ECG rhythm analysis; detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, inconclusive and unreadable rhythm. The Frontier X Plus is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms requiring cardiac monitoring. The device has not been tested for pediatric use. The Frontier X Plus is a prescription-only device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.

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

510(k) Notification K240794

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

Fourth Frontier Technologies Private Limited
2nd and 3rd Floor, No. 794,
12th Main, 1st Cross,
HAL 2ndStage
Indiranagar, Bengaluru, 560038
Karnataka, India
Phone: +1- 512-8817266

Applicant Contact Person:

Manav Bhushan
CEO
Fourth Frontier Technologies Private Limited

Email: manav@fourthfrontier.com

Date Prepared: November 4, 2024

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Frontier X Plus

Generic/Common Name:

Medical Magnetic Tape Recorder

Classification:

21 CFR§870.2800, Medical Magnetic Tape Recorder, Class II

Product Code:

MLO

Subsequent Product Code(s): DXH , DPS

PREDICATE DEVICE(S) [807.92(a)(3)]

K201644 – QardioCore ECG Monitor (primary predicate device) **Product code:** DSH

K182396 – AliveCor Heart Monitor (predicate device, currently marketed as “KardiaMobile”)

Product code: DXH, DPS

510(k) Summary

DEVICE DESCRIPTION [807.92(a)(4)]

The Frontier X Plus is an ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes a proprietary algorithm, to analyze single-channel ECG. The Frontier X Plus hardware transmits the ECG signal from a dry electrode array embedded in the Frontier X Plus chest strap to the embedded Frontier X Plus firmware, integrated with the HeartKey ECG algorithm to be analyzed and presented to the user. All ECGs are synced with the user's account.

INDICATIONS FOR USE [807.92(a)(5)]

The Frontier X Plus device is an ambulatory monitoring device intended to record, store, and transfer single-channel (ECG) rhythms for monitoring and evaluation. The Frontier X Plus system also displays ECG waveforms and ECG rhythm analysis; detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, inconclusive and unreadable rhythm. The Frontier X Plus is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms requiring cardiac monitoring. The device has not been tested for pediatric use. The Frontier X Plus is a prescription-only device, and the reported information is provided for review by a physician, who will render a diagnosis based on clinical judgment and experience.

510(k) Summary

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE[807.92(a)(6)]

Feature	Frontier X Plus	QardioCore ECG Monitor	KardiaMobile, KardiaStation System
510(k)	K240794	K201644	K182396
Regulation Number(s)	***21 CFR 870.2800***	***21 CFR 870.2800***	***21 CFR 870.2920*** ***21 CFR 870.2340***
Regulation Name	• Medical Magnetic Tape Recorder	• Medical Magnetic Tape Recorder	• Transmitters And Receivers, Electrocardiograph, Telephone • Electrocardiograph
Regulatory Class	Class II	Class II	Class II
Classification Product Code	MLO	DSH	DXH
Subsequent Product Code(s)	DXH, DPS	N/A	DPS
Over The Counter	No	No	Yes
Indications for use	The Frontier X Plus device is an ambulatory monitoring device intended to record, store, and transfer single-channel (ECG) rhythms for monitoring and evaluation. The Frontier X Plus system also displays ECG waveforms and ECG rhythm analysis; detecting the presence of normal sinus rhythm,	The QardioCore ECG ambulatory monitoring device is intended to capture, store, transmit, and display ECG information for recording periods of up to 24-hours in a single session. It is indicated for use on adult patients who may be asymptomatic or who meet clinical indications to perform an ECG-Holter monitor exam. The QardioCore ECG monitor is a prescription-only	The KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile system also displays ECG rhythms and output of ECG analysis from AliveCor's KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others when prescribed or used under the care of a healthcare professional.

510(k) Summary

Feature	Frontier X Plus	QardioCore ECG Monitor	KardiaMobile, KardiaStation System
	atrial fibrillation, bradycardia, tachycardia, inconclusive and unreadable rhythm. The Frontier X Plus is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms requiring cardiac monitoring. The device has not been tested for pediatric use. The Frontier X Plus is a prescription-only device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.	device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.	The KardiaMobile System is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. The device has not been tested and is not intended for pediatric use.
Mechanism of Action	User completes circuit with skin contact and hardware transmits	User completes circuit with skin contact and	User completes circuit with skin contact and hardware transmits signal to

510(k) Summary

Feature	Frontier X Plus	QardioCore ECG Monitor	KardiaMobile, KardiaStation System
	signal to Frontier X Plus firmware to convert and display ECG waveform	hardware transmits signal to Frontier X Plus firmware to convert and display ECG waveform	Frontier X Plus firmware to convert and display ECG waveform
Where used (intended use)	Mobile/active users at rest (ambulatory)	Mobile/active users at rest (ambulatory)	Mobile/active users at rest (ambulatory)
Anatomical sites	On or below chest	On or below chest	Left hand fingers to right hand fingers Left leg to right hand fingers On or below chest
Available Algorithms	Atrial Fibrillation Unreadable Normal Sinus Rhythm Tachycardia Bradycardia Inconclusive	None	Atrial Fibrillation Noise Algorithm (Unreadable/Inconclusive) Normal Sinus Rhythm Tachycardia Bradycardia
Data Acquisition: Frequency Response	0.05 Hz to 40 Hz	0.5 to 40 Hz	0.5 Hz to 40 Hz
ECG electrodes	Dry electrodes (Chest strap - single use)	Dry electrodes	Dry electrodes
ECG channels	Single Channel	Single Channel	Single Channel
Resolution	16 bits	18 bits	16 bits
Sample Rate	500 samples / second (500 Hz)	125 samples / second (125Hz)	300 samples/second
Number of ECG Leads	Single lead, 2 electrodes	Single lead, 2 electrodes	Single lead, 2 electrodes
Power Supply: Battery	3.7V Li-Polymer Battery (rechargeable)	3.7V Li-Polymer Battery (rechargeable)	3.7V Li-Polymer Battery (rechargeable)
Battery Life (typical)	3 years (500 full charges)	2 years	2 years (100 hours)
User Interface: Primary Lead Data acquisition Hardware Software interface	Chest Strap to Apple iOS-based or Google Android-based software via Bluetooth and via embedded Frontier X Plus software	Chest Strap to Apple iOS-based or Google Android-based software via Bluetooth	Lead I, Left to Right Ultrasonic acoustics Two-electrode sensor Apple iOS-based or Google Android-based software

510(k) Summary

Feature	Frontier X Plus	QardioCore ECG Monitor	KardiaMobile, KardiaStation System
Physical Specs: Dimensions Weight	74mm x 26mm x 14mm 23g (without strap)	185mm x 87mm x 9mm 130g (including strap)	82mm x 32mm x 4mm 15g
Prescribed:	Prescription	Prescription	Prescription and OTC
Communications	Bluetooth	Bluetooth	Ultrasonic Acoustics acquired by phone

SUBSTANTIAL EQUIVALENCE

The Frontier X Plus subject device has the same intended use and similar technological characteristics as the QardioCore ECG Monitor predicate device. The differences in technological characteristics have been analyzed and addressed through performance testing. The evaluation and testing results showed that differences between the subject and predicate device do not raise different questions of safety or effectiveness.

PERFORMANCE DATA [807.92(b)]

All necessary performance testing was conducted on the Frontier X Plus to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Nonclinical Testing Summary:

All necessary performance testing was conducted on the Frontier X Plus to support a determination of substantial equivalence to the predicate device. This testing included the following:

- Cybersecurity Testing
- Verification against the device's specifications
- Software verification and validation
- Signal integrity testing to evaluate impact of cleaning and aging
- Frontier X Plus validation using real-world data, supplementary clinical investigation data and human factors data
- Evaluation to the following standards:
    - ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
    - ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
    - International Standard ISO 10993 Fourth edition: 2021-11, Biological Evaluation of Medical Devices Part 10: "Tests for Skin Sensitization". Reference Number: ISO 10993 -10:2021 (E).

510(k) Summary

- International Standard ISO 10993 First edition: 2021-01, Biological Evaluation of Medical Devices Part 23: "Tests for Irritation". Reference Number: ISO 10993 -23:2021 (E).
- IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance,
- ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence.
- FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- IEC 60601-1-2:2014+AMD1: 2020 CSV, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests,
- IEC 60601-1-11:2015, Medical electrical equipment -- Part 1-11: 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, and
- IEC 60601-2-47:2012, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems.
- ANSI/AAMI EC57: 2012, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms (K200884)

[807.92(b)(1)] Clinical Testing Summary:

The Clinical Investigation Study was conducted in a population consistent with the subject device's indications for use. The study's objectives included a comparative evaluation of the clinical equivalence of ECG waveforms recorded by the subject device to simultaneously captured ECG waveforms from a reference device (Standard 12-lead ECG). The study further evaluated the reliability of the Frontier X Plus ECG rhythm analysis software algorithm by assessing its ability to detect and classify Atrial fibrillation, Normal Sinus Rhythm, Tachycardia, Bradycardia, Inconclusive and noisy/unreadable signals, from all the ECG recordings obtained on the subject device, when compared to simultaneously acquired signals from a standard 12-lead ECG device. ECGs from the subject and reference devices were collected and analyzed at various time points representative of normal subject and reference device use. Various quantitative and qualitative metrics including relevant ECG waveform characteristics were measured and analyzed. The data provided demonstrated the substantial equivalence with the predicate device. The collective results of the performance testing demonstrate that the Frontier X Plus meets the established specifications and complies with the aforementioned standards.

A total of 832 users were included in the Study population. This included approximately 30% data

510(k) Summary

from Females, 70% from Males, and approximately 66% from White/Caucasians, 5% Hispanic/Latino, 19% Asian, 5% Black and 4% other ethnic groups. As far as Age distribution is concerned, approximately 22% of Users were aged between 18-44, 56% were between 45-65 and 22% were 65 yrs and over. Of the total set of users that were part of the study population, 32% of users, i.e., 264 users had recorded episodes of Atrial Fibrillation. In terms of BMI, approximately 10% of users were below a BMI of 21, 40% had a BMI between 21 and 25, and 50% had a BMI greater than 25.

SUMMARY

The Frontier X Plus subject device has the same intended use and similar technological characteristics as the QardioCore ECG Monitor predicate device. The differences in technological characteristics have been analyzed and addressed through performance testing. The evaluation and testing results showed that differences between the subject and predicate device do not raise different questions of safety or effectiveness. The Frontier X Plus is substantially equivalent to the predicate device.