December 18, 2024

Viasonix Ltd.
Dan Manor
CEO
10 Hamelacha Street
Ra'anana, 4366105
Israel

Re: K242662
Trade/Device Name: Falcon/Xpress (Falcon/Xpress)
Regulation Number: 21 CFR 870.2880
Regulation Name: Ultrasonic Transducer
Regulatory Class: Class II
Product Code: JOP
Dated: August 25, 2024
Received: September 4, 2024

Dear Dan Manor:

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242662

Device Name

Falcon/Xpress

Indications for Use *(Describe)*

The Falcon/Xpress is intended for use in the noninvasive evaluation of peripheral vascular pathology in patients.
The Falcon/Xpress is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.
The Falcon/Xpress is to be used only by trained medical personnel in hospitals, clinics and physicians' offices by prescription or doctor's orders

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.

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510(K) SUMMARY

1. ADMINISTRATIVE INFORMATION

Date:	1-Aug-2024
Submitter:	Viasonix Ltd. 10 Hamelacha Street Raanana, ISRAEL 4366105 Phone: 972-9-7441692
Official Correspondent:	Dr. Dan Manor, CEO
Trade Name:	Falcon/Xpress
Classification Name:	Ultrasonic transducer
Classification Number:	21 CFR 870.2880
Product Code:	JOP
Device Class:	Class II
Predicate Devices:	Falcon - K111416

2. DEVICE DESCRIPTION

The Falcon/Xpress is intended for use in the noninvasive evaluation of peripheral vascular pathology in patients . The Falcon/Xpress is a new model that is added to the cleared Falcon product family (K111416), which already includes the Falcon/Pro, Falcon/Quad and Falcon/ABI+ models. The Falcon/Xpress is similar to the other Falcon models in terms of technology, operation, software, intended use, applications, and accessories. The main differences are that the Falcon/Xpress supports 2 independent pressure channels (compared to 10 for the Pro and 4 for the Falcon/Quad and Falcon/ABI+), 2 PPG sensors (compared to 5 for the Pro and 4 for the Quad and ABI+), 2 Doppler ports (compared to 3 for the Pro and Quad and 0 for the ABI+), and no temperature sensor (compared to 1 for the Pro, Quad and ABI+). In addition, the Falcon/Xpress supports operation with an external battery and supports an 8-channel pressure selector (not available with the other Falcon models). The Falcon/Xpress supports an optional tablet, and can be mounted on a cart or within a dedicated bag.

The Falcon/Xpress system is smaller in size, with dimensions of roughly 27x20x5.5 cm, compared to the Falcon legacy models with dimensions of 34x31x9.5 cm. In addition, the Falcon/Xpress system weighs roughly 2 kg, compared to roughly 4 kg for the Falcon legacy models.

Similar to the other Falcon models, the Falcon/Xpress is based on pneumatic technology to measure systolic blood pressures and Pulse Volume Recording waveforms (PVR) at

various peripheral limb sites. Similarly, the Falcon/Xpress includes the same Continuous Wave (CW) Doppler technology as the other Falcon models to allow measurements of blood flow velocities in peripheral blood vessels. The Falcon/Xpress also supports the same Photo-Plethysmography technology (PPG) as the other cleared Falcon models.
The above-mentioned technologies allow the Falcon/Xpress to perform peripheral vascular diagnosis measurements in a similar manner to the cleared Falcon models (K111416), including the measurements of segmental systolic blood pressures, the Ankle-Brachial pressure index, PVR measurement, PPG measurements, and blood flow velocity measurements. The measurements support dedicated specialty test protocols such as measurements under various stress conditions, thoracic outlet syndrome, raynaud's syndrome, pulse wave velocity, penile function, venous reflux, venous capacitance and outflow, palmar arch test, arterio-venous fistula, and similar. All of the specialty tests simply use the measurements according to dedicated protocols and display for the evaluation of specific medical conditions.

The pressure cuffs are connected to the air tubes via "Bayonet" connectors or Viasonix V-fit connectors. Both of these options are designed to avoid potential misconnections by being incompatible with standard Luer connectors or other connectors used for non-vascular applications.

3. INTENDED USE AND INDICATIONS FOR USE

The Falcon/Xpress is intended for use in the noninvasive evaluation of peripheral vascular pathology in patients.
The Falcon/Xpress is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.
The Falcon/Xpress is to be used only by trained medical personnel in hospitals, clinics and physicians' offices by prescription or doctor's orders

4. SUMMARY OF TECHNICAL CHARACTERISTICS

The Falcon/Xpress is similar to the predicate device cited above in technology, function, software platform, intended use, applications, and accessories.

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, the intended use, use environment and target patient population of the Falcon/Xpress, are substantially equivalent to the predicate device cited above.

4.1 Summary Table of Comparison

Feature	Falcon/Pro	Falcon/Quad	Falcon/ABI+	Falcon/Xpress	Discussion of Differences
510(k) number	K111416			This application	
Regulation Number / Product Code	21 CFR 870.2880 / JOP			21 CFR 870.2880 / JOP	Identical
Indications for use	The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ are intended for use in the noninvasive evaluation of peripheral vascular pathology in patients. The devices are not intended to replace other means of evaluating vital patient physiological processes, are not intended to be used in fetal applications, and are not intended to be used inside the sterile field. They are to be used by trained medical personnel in hospitals, clinics and physicians' offices by prescription or doctor's orders.			The Falcon/Xpress is intended for use in the noninvasive evaluation of peripheral vascular pathology in patients. The Falcon/Xpress is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field. The Falcon/Xpress is to be used only by trained medical personnel in hospitals, clinics and physicians' offices by prescription or doctor's orders.	Identical, except the product model refers to Xpress
Pressure channels	10	4	4	2 or 8	Equivalent All pressure channels are completely independent and perform exactly the same without any dependency on the total number of pressure channels. Additional pressure channels simply help the operator when preparing the patient but have no effect on the performance or clinical outcome. In the Falcon/Xpress, there are 2 default pressure channels, which can be extended to a total of 8 pressure channels by connection to an external pressure channels selector. The performance of each channel is identical to the

Feature	Falcon/Pro	Falcon/Quad	Falcon/ABI+	Falcon/Xpress	Discussion of Differences
					others. No impact on the indications for use.
Simultaneous PVR measurements	10	4	4	2	Equivalent All pressure channels are completely independent and perform exactly the same PVR measurements without any dependency on the total number of pressure channels. Additional pressure channels just help the operator when preparing the patient for PVR measurements but have no effect on the performance or clinical outcome. In the Falcon/Xpress there are simply fewer PVR pressure channels, which require the operator to connect the pressure tubes to other sites after completing a measurement, similar to the Falcon/Quad or Falcon/ABI+ compared to the Falcon/Pro. No impact on product performance and effectiveness
PPG sensors	5	4	4	2	Equivalent The PPG ports are completely independent, and the performance and measurements made by each PPG sensor are identical, regardless of the number of PPG ports available. The Falcon/Xpress is capable of performing up to 2 simultaneous PPG measurements, compared to the Falcon/Quad or Falcon/ABI+, which can perform 4 simultaneous measurements or the Falcon/Pro with 5 simultaneous PPG measurements. There is no clinical requirement to perform simultaneous PPG measurements, and it is primarily to help the operator. No impact on product performance and effectiveness
Doppler probes	4, 8 and 10 MHz CW	4, 8 and 10 MHz CW	N/A	4, 8 MHz CW	Identical This is identical to the Falcon/Pro and Falcon/Quad. The 10

Feature	Falcon/Pro	Falcon/Quad	Falcon/ABI+	Falcon/Xpress	Discussion of Differences
					MHz CW probe performs similar to the 8MHz probe on the same sites and does not change the intended use. The Falcon/Xpress does not support the 10MHz probe.
Temperature measurement	yes	yes	yes	no	Temperature measurement is not a requirement for the vascular applications. The Falcon/Xpress does not include the temperature sensor because it can measure skin temperature using other methods if necessary. The absence of an integrated skin temperature sensor has no effect on the Falcon/Xpress intended use or performance.
Specialty tests	Stress, TOS, raynaud's, penile function, venous reflux, venous capacitance and outflow, palmar arch test, arterio-venous fistula, popliteal entrapment	Stress, TOS, raynaud's, penile function, venous reflux, venous capacitance and outflow, palmar arch test, arterio-venous fistula, popliteal entrapment	Stress, TOS, raynaud's, penile function, venous reflux, venous capacitance and outflow, palmar arch test, arterio-venous fistula, popliteal entrapment	Stress, TOS, raynaud's, pulse wave velocity, penile function, venous reflux, venous capacitance and outflow, palmar arch test, arterio-venous fistula, popliteal entrapment	Equivalent Same, except pulse wave velocity, which is added and is simply the distance between 2 pressure cuffs divided by the time difference between the end of diastole in the PVR waveform for those cuffs. The addition of the pulse wave velocity test does not impact the Falcon/Xpress indications for use.
Remote control operation	yes	yes	yes	yes	Identical
Touch screen controls	yes	yes	yes	yes	Identical
Foot switch controls	yes	yes	yes	yes	Identical
Mouse and keyboard controls	yes	yes	yes	yes	Identical
Control of target inflation pressures	yes	yes	yes	yes	Identical
Control of pressures deflation rate	yes	yes	yes	yes	Identical
Acoustic testing	track 1	track 1	N/A	track 1	Identical to Falcon/Pro and Falcon/Quad

Feature	Falcon/Pro	Falcon/Quad	Falcon/ABI+	Falcon/Xpress	Discussion of Differences
Doppler spectral analysis	yes, 256-point FFT	yes, 256-point FFT	N/A	yes, 256-point FFT	Identical to Falcon/Pro and Falcon/Quad
Bidirectional Doppler, invert function	yes	yes	N/A	yes	Identical to Falcon/Pro and Falcon/Quad
Doppler volume controls	yes	yes	N/A	yes	Identical to Falcon/Pro and Falcon/Quad
Doppler envelope	upper, lower, both, none	upper, lower, both, none	N/A	upper, lower, both, none	Identical to Falcon/Pro and Falcon/Quad
Calculated blood pressure parameters	ABI, segmental pressure indices	ABI, segmental pressure indices	ABI, segmental pressure indices	ABI, segmental pressure indices	Identical
Calculated Doppler parameters	Peak velocity, mean velocity, diastolic velocity, PI, RI, S/D, RT, HR	Peak velocity, mean velocity, diastolic velocity, PI, RI, S/D, RT, HR	N/A	Peak velocity, mean velocity, diastolic velocity, PI, RI, S/D, RT, HR	Identical to Falcon/Pro and Falcon/Quad
Calculated venous reflux test parameters	Venous refill time	Venous refill time	Venous refill time	Venous refill time	Identical
Calculated MVO/SVC test parameters	MVO/SVC ratio	MVO/SVC ratio	MVO/SVC ratio	MVO/SVC ratio	Identical
Backup options	DVD, USB storage device	DVD, USB storage device	DVD, USB storage device	DVD, USB storage device	Identical
Dicom connectivity	available	available	available	available	Identical
Printer support	Most commercial printers	Most commercial printers	Most commercial printers	Most commercial printers	Identical
Customized examination protocols	available	available	available	available	Identical
Configuration of printed reports	available multiple options	available multiple options	available multiple options	available multiple options	Identical
Patient details	full, with patient history	full, with patient history	full, with patient history	full, with patient history	Identical
Database search options	By name, ID number, date, and other examination details	By name, ID number, date, and other examination details	By name, ID number, date, and other examination details	By name, ID number, date, and other examination details	Identical
Online help	available	available	available	available	Identical
Standards Compliance	IEC 60601-1, IEC 60601-1-2,	IEC 60601-1, IEC 60601-1-2, IEC	IEC 60601-1, IEC 60601-1-2, IEC	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC	Identical The Falcon/Xpress meets

Feature	Falcon/Pro	Falcon/Quad	Falcon/ABI+	Falcon/Xpress	Discussion of Differences
	IEC 60601-2-37, ISO10993-1, ISO 80369-1	60601-2-37, ISO10993-1, ISO 80369-1	60601-2-37, , ISO10993-1, ISO 80369-1	62133-2, ISO 10993-1, ISO 80369-1	the recent FDA consensuses standards
Acoustic Track	FDA Tack 1	FDA Tack 1	FDA Tack 1	FDA Tack 1	Identical
External battery	No	No	No	Yes	The external battery in Falcon/Xpress allows operating the system with an external battery for at least 2 hours while not connected through the external power supply to the mains. This has no impact on the indications for use.
Proposed accessories	Cuffs, PPG, Doppler Probe, Wired and IR Remote control, Foot Switch, Keyboard and Mouse	Cuffs, PPG, Doppler Probe, Wired and IR Remote control, Foot Switch, Keyboard and Mouse	Cuffs, PPG, Doppler Probe, Wired and IR Remote control, Foot Switch, Keyboard and Mouse	Cuffs, PPG, Doppler Probe, Wired and IR Remote control, Foot Switch, External battery, Pressure selector, Cart, Carrying bag, tablet, cart, Keyboard and Mouse	Equivalent The Falcon/Xpress shares the same accessories as the predicate device. In addition, the proposed Falcon/Xpress includes an external battery, pressure channels selector, carrying bag, and the use of an optional tablet and cart, which do not impact the indication for use.

5.1 UTILIZATION OF STANDARDS AND GUIDANCES:

The Falcon/Xpress meets the following standards and guidances:

1. IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. IEC 60601-2-37 - Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
4. ISO 80369-1 - Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
5. ISO 10993-1 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6. Guidance for Industry and FDA Staff Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: February 2023

5.2 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Summary of Non-Clinical Tests:

The Falcon/Xpress device has been subjected to bio-compatibility, electrical safety, mechanical safety, acoustic output, EMC emissions and immunity, by certified laboratories. Internally, the Falcon/Xpress device was subjected to full software verification, validation, and performance testing to ensure that the device met all of its functional specifications.

5.3 SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical study was conducted to support this application.

5.4 CONCLUSIONS

Based on its underlying technology and bench tests performed, the Falcon/Xpress is substantially equivalent to the predicate device.