May 16, 2019

Viasonix Ltd.
% Shlomi Deler
Regulatory Affairs
10 Hamelacha Street
Raanana, 4366105
ISRAEL

Re: K191023
Trade/Device Name: Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX
Dated: April 10, 2019
Received: April 24, 2019

Dear Shlomi Deler:

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 (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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

K191023

Device Name
Dolphin/IQ, Dolphin/4D and Dolphin/MAX

Indications for Use *(Describe)*

Dolphin/IQ, Dolphin/4D and Dolphin/MAX are medical Doppler devices intended for noninvasive measurements of blood flow velocities in arteries and veins in adults and Pediatric. The Dolphin systems can be used in hospitals, clinics and physician offices

Contraindications : The Dolphin is not intended to be used in fetal or neonatal applications.

Note : The Dolphin is to be used only by trained medical personnel.

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.

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Indications For Use Form

System: Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Transducer: 1.6 MHz Hand Held

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic			x				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			x				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			x				
	Other (Specify)							

Indications For Use Form

System: Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Transducer: 2 MHz Hand Held

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic			x				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			x				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			x				
	Other (Specify)							

Indications For Use Form

System: Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Transducer: 2 MHz Monitoring

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic			x				
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			x				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			x				
	Other (Specify)							

Indications For Use Form

System: Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Transducer: 4 MHz Hand Held

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic			x	x			
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			x	x			
	Other (Specify)							

Indications For Use Form

System: Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Transducer: 8 MHz Hand Held

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic			x	x			
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel			x	x			
	Other (Specify)							

SECTION 5 – 510(K) SUMMARY K191023

5.1 ADMINISTRATIVE INFORMATION

Date:	10-April-2019
Submitter:	Viasonix Ltd. 10 Hamelacha Street Raanana , ISRAEL 4366105 Phone : 972-9-7441692
Official Correspondent:	Dan Manor, CEO
Trade Name:	Dolphin/IQ, Dolphin/4D and Dolphin/MAX
Classification Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Number:	21 CFR 892.1550
Product Code:	IYN, ITX
Device Class:	Class II
Predicate Devices:	Dolphin/IQ and Dolphin/4D, K170859

5.2 DEVICE DESCRIPTION

Dolphin/IQ, Dolphin/4D and Dolphin/MAX systems are part of the Dolphin product family of non-invasive peripheral vascular diagnostic systems. The Dolphin/IQ, Dolphin/4D and Dolphin/MAX are transcranial Doppler (TCD) systems for measurement of blood flow velocity intracranially, extracranially and in the peripheral circulation. Both systems share identical Doppler hardware and software. The Dolphin/IQ is a module, that needs to connect to an external computer and display for its' operation while the Dolphin/4D is a complete integrated system that includes and integrated computer system with hard disk, and touch screen display. Dolphin/Max is similar to the Dolphin/4D system, except that it also has an internal rechargeable battery and an external power supply. The functionality and performance of Dolphin/IQ, Dolphin/4D and Dolphin/MAX systems is identical. Dolphin systems support the same Doppler probes: 1.6 MHz PW hand held probe, 2 MHz PW hand held probe, 2 MHz PW monitoring probe, 4 MHz CW/PW hand held probe and 8 MHz CW/PW hand held probe. Dolphin systems support the same accessories: IR wireless remote control, External Channels connection box, wired remote control foot switch and monitoring head set.
Wherever the term Dolphin is used in this document, it applies to the Dolphin/IQ, Dolphin/4D and Dolphin/MAX. Otherwise, each product is specified specifically by name.

The Dolphin devices are based on Doppler technology and are designed for standard intended use for Transcranial Doppler systems operated only by experienced medical staff.

5.3 INTENDED USE AND INDICATIONS FOR USE

The Dolphin/IQ, Dolphin/4D and Dolphin/MAX are medical Doppler devices intended for noninvasive measurements of blood flow velocities in arteries and veins in adults and Pediatric. The Dolphin systems can be used in hospitals, clinics and physician offices.

Contraindications: The Dolphin is not intended to be used in fetal or neonatal applications.

Note - The Dolphin is to be used only by trained medical personnel

5.4 SUMMARY OF TECHNICAL CHARACTERISTICS

The Dolphin/IQ, Dolphin/4D and Dolphin/MAX devices are similar to the predicate device cited above [section 5.1] with 1.6MHz, 2MHz, 4MHz and 8MHz transducers intended for transcranial and peripheral Doppler applications.

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 Dolphin/IQ, Dolphin/4D and Dolphin/MAX devices is substantially equivalent to the predicate device cited above.

5.4.1 Summary table of Comparison

Specification	Dolphin/4Q, Dolphin/IQ and Dolphin/MAX	Dolphin/4D and Dolphin/IQ	Differences discussion
510(k) number	Proposed Device	K170859	NA
Manufacturer	VIASONIX LTD.	VIASONIX LTD.	NA
Product regulation and code	21 CFR 892.1550 Code: IYN, ITX	21 CFR 892.1550 Code: IYN, ITX	Identical to predicate
Indications for use	The Dolphin/IQ, Dolphin/4D and Dolphin/MAX are medical Doppler devices intended for noninvasive measurements of blood flow velocities in arteries and veins in adults and Pediatric. The Dolphin systems can be used in hospitals, clinics and physician offices.	The Dolphin/IQ and Dolphin/4D are medical Doppler devices intended for noninvasive measurements of blood flow velocities in arteries and veins in adults and Pediatric. The Dolphin systems can be used in hospitals, clinics and physician offices.	Identical The Dolphin/MAX model was added with this submission. Intended use, use environment and target patient population is identical to the predicate device.
Clinical Applications	Intracranial Extracranial Peripheral	Intracranial Extracranial Peripheral	Identical
Weight (kg)	Dolphin/4D: ~6 Kg Dolphin/IQ: ~2 Kg Dolphin/MAX:~ 6 Kg	Dolphin/4D: ~6 Kg Dolphin/IQ: ~2 Kg	Identical to Dolphin/4D
Dimensions (cm)	Dolphin/4D: 47x30x7 Dolphin/MAX: 47x30x7 Dolphin/IQ: 26.5x20.5x5.5	Dolphin/4D: 47x30x7 Dolphin/IQ: 26.5x20.5x5.5	-Dolphin/MAX is similar to Dolphin/4D
Frequency modes / Transducers (MHz)	1.6MHz PW 2MHz PW 4MHz PW/CW 8MHz PW/CW	1.6MHz PW 2MHz PW 4MHz PW/CW 8MHz PW/CW	Identical
Patient surface contact materials	Compatible	Compatible	Identical
2 MHz Monitoring Probe	available	available	Identical
Monitoring headset	available	available	Identical

Specification	Dolphin/4Q, Dolphin/IQ and Dolphin/MAX	Dolphin/4D and Dolphin/IQ	Differences discussion
User controls	Remote control, foot switch, touch screen, key board, mouse	Remote control, foot switch, touch screen, key board, mouse	Identical
Display modes	Unilateral, bilateral, monitoring, external channels, HITS	Unilateral, bilateral, monitoring, external channels, HITS	Identical
Sample Volume (2 MHz)	1-20 mm	1-20 mm	Identical
Scale (2 MHz)	Up to 32 KHz depth dependent	Up to 32 KHz depth dependent	Identical
Power control	0-100 % of maximal derated I_{spta} within FDA guidelines	0-100 % of maximal derated I_{spta} within FDA guidelines	Identical
Maximal Acoustic $I_{spta.3}$ (mW/cm^2)	Below maximal FDA guideline limits Comply with FDA limits: $I_{spta.3} \leq 720$ mW/cm^2 MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 W/cm^2.	Below maximal FDA guideline limits Comply with FDA limits: $I_{spta.3} \leq 720$ mW/cm^2 MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 W/cm^2.	Identical
M-mode display	available	available	Identical
Multi-gate windows	Up to 8	Up to 8	Identical
HITS detection	Available	Available	Identical
Velocity profile display	Available	Available	Identical
Cursors	Available	Available	Identical
Audio replay	Available	Available	Identical
Sweep time display	Up to 3 minutes	Up to 3 minutes	Identical
Parameters	Peak velocity, mean velocity, end diastolic velocity, pulsatility Index, resistance index, systolic to diastolic ratio, rise time, heart rate	Peak velocity, mean velocity, end diastolic velocity, pulsatility Index, resistance index, systolic to diastolic ratio, rise time, heart rate	Identical
Measurement accuracy	± 10% accuracy	± 10% accuracy	Identical
accessories	Remote control, foot switch, monitoring head set, External Channels connection box, Wired remote control	Remote control, foot switch, monitoring head set	Equivalent. The added accessories don't impact product performance and effectiveness
Velocity units	Cm/sec or KHz	Cm/sec or KHz	Identical
Summary screens	available	available	Identical
Patient database	available	available	Identical

Specification	Dolphin/4Q, Dolphin/IQ and Dolphin/MAX	Dolphin/4D and Dolphin/IQ	Differences discussion
Patient search options	available	available	Identical
Spectrum color palette selection	available	available	Identical
Insonation angle	User defined	User defined	Identical
Database backup options	available	available	Identical
Database statistics	available	available	Identical
Export	Multiple formats	Multiple formats	Identical
Analog input channels	8	8	Identical
Analog output channels	4	4	Identical
Configurable protocols	available	available	Identical
Specialty tests	available	available	Identical
Connectivity to PACS systems	available	available	Identical
Printer support	available	available	Identical
Standards Compliance	IEC 60601-1 , 3.1 Ed. IEC 60601-1-2. 4 Ed. IEC 60601-2-37. 2.1 Ed.	IEC 60601-1 , 3.1 Ed. IEC 60601-1-2. 4 Ed. IEC 60601-2-37. 2.1 Ed.	Identical
Power Input	Dolphin/4D 100-240V, 50/60 Hz, 1.5A max. Dolphin/IQ 12VDC, 5A. Dolphin/MAX External 15VDC, 9.6A or internal battery	Dolphin/4D 100-240V, 50/60 Hz, 1.5A max. Dolphin/IQ 12VDC, 5A.	Dolphin/MAX is similar to Dolphin/4D which provides additional internal rechargeable battery option. No impact to product performance and effectiveness
Battery Operating Time	At least 3 hours of routine examination [applicable only to Dolphin/MAX]	NA	The Dolphin/MAX is capable to operate with internal rechargeable battery with no impact to product performance and effectiveness

5.5 UTILIZATION OF STANDARDS AND GUIDANCE'S:

The Dolphin/IQ, Dolphin/4D and Dolphin/MAX meets the following standards and guidance's:

1. IEC 60601-1:2005+A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014 - 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: 2007(AMD1:2015) [Edition 2.1] - Medical Electrical Equipment - Part 2-37: Particular Requirements for The Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3
5. UD 3-2004 (R2009) - Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. Revision 2.
6. Guidance for Industry and FDA Staff Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: September 9, 2008
7. IEC 62366-1: 2015 - Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
8. IEC 60601-1-6: 2013 [Edition 3.1] - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

5.6 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Summary of Non-Clinical Tests:

The Dolphin/IQ, Dolphin/4D and Dolphin/MAX devices have been thoroughly tested through verification of specifications and validation, including software validation.

5.7 SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical study was conducted to support this application.

5.8 CONCLUSIONS

Based on its underlying technology and bench tests performed, the Dolphin/IQ, Dolphin/4D and Dolphin/MAX are substantially equivalent to the predicate device.