Viasonix Ltd.
Dan Manor, CEO
10 Hamelacha Street
Raanana, 4366105
ISRAEL

January 29, 2021

Re: K202742
Trade/Device Name: Dolphin/IQ, Dolphin/4D and Dolphin/MAX with Dolphin/XF Robot Accessory
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, OQQ

Dear Dan Manor:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 25, 2021. Specifically, FDA is updating this SE Letter as an administrative correction because the 510(k) Summary was not included in the SE package.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thalia Mills, OHT7: Office of In Vitro Diagnostics and Radiological Health by email (Thalia.Mills@fda.hhs.gov) or phone (301-796-6641).

Sincerely,

Michael D. O'Hara For

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

Viasonix Ltd.
℅ Mr. Dan Manor, CEO
10 Hamelacha Street
Raanana, 4366105
ISRAEL

January 25, 2021

Re: K202742
Trade/Device Name: Dolphin/IQ, Dolphin/4D and Dolphin/MAX with Dolphin/XF Robot Accessory
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, OQQ
Dated: December 23, 2020
Received: December 30, 2020

Dear Mr. 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 (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/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 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 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,

Michael D. O'Hara For

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)*
K202742

Device Name
Dolphin/IQ, Dolphin/4D and Dolphin/MAX with the Dolphin/XF robot accessory

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

The Dolphin/XF robot accessory, when used with the Dolphin system, is a device which assists the user in the acquisition of cerebral blood flow velocity.

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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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."

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

5.1 ADMINISTRATIVE INFORMATION

K202742

Date:	22-January-2021
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 with Dolphin/XF robot accessory
Primary Classification:	
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System
Regulation Number:	21 CFR 892.1550, Product Code: IYN
Secondary Classification:	
Regulation Name:	Diagnostic Ultrasonic Transducer,
Regulation Number:	21 CFR 1570, Product Codes: ITX, OQQ
Device Class:	Class II
Primary Predicate Device:	Dolphin/IQ , Dolphin/4D and Dolphin/MAX, K191023
Reference Device:	EMS9UA, K122710

5.2 DEVICE DESCRIPTION

Dolphin/IQ, Dolphin/4D and Dolphin/MAX systems are part of the Dolphin product family of transcranial Doppler 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. All 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 an 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, monitoring head set and Dolphin/XF robot.

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.

The Dolphin supports the Dolphin/XF robot accessory. The Dolphin/XF robot accessory, when used with the Dolphin system, is a device which assists the user in the acquisition of cerebral blood flow velocity. This accessory can be unilateral or bilateral, and is attached to the head with a dedicated headset. It is software controlled, and allows scanning in two angular directions in order to assists the user in the acquisition of the cerebral blood flow velocity.

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.

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The Dolphin/XF robot accessory, when used with the Dolphin system, is a device which assists the user in the acquisition of cerebral blood flow velocity

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 devices cited above with 1.6MHz, 2MHz, 4MHz and 8MHz transducers intended for transcranial and peripheral vascular Doppler applications and with the Dolphin/XF robot accessory.

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 with the Dolphin/XF robot accessory is substantially equivalent to the predicate devices cited above.

5.4.1 Summary table of Comparison

Specification	Dolphin devices [4D, IQ and MAX] with Dolphin/XF Robot accessory	Dolphin devices [4D, IQ and MAX] / EMS9UA with Roboprobe Headband [Predicate devices]	Differences discussion
510(k) number	Proposed Device	K191023 / K122710	NA
Manufacturer	VIASONIX LTD.	VIASONIX LTD. / Shenzhen Delicate Electronics	NA
Product regulation and code	21 CFR 892.1550 Code: IYN, ITX and OQQ	21 CFR 892.1550 Code: IYN, ITX / 21 CFR 892.15 70 Code: IYN, ITX and OQQ	IYN and ITX identical to Dolphin predicate OQQ is identical to EMS9UA reference device
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/XF robot accessory, when used with the Dolphin system, is a device which assists the user in the acquisition of cerebral blood flow velocity.	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. / Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system. The Roboprobe Headband facilitates monitoring use by its ability to track the Doppler signal	Identical to the Dolphin predicate with the extended indication to assists the user in the acquisition of cerebral blood flow velocity. This indication is similar to a reference device, the NeuralBot , K180455 under the same product code: OQQ . The NeuralBot when used with Lucid M1 System is a medical ultrasound device which assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows
Clinical Applications	Intracranial Extracranial Peripheral	Intracranial Extracranial Peripheral	Identical to Dolphin predicate device
Weight (kg)	Dolphin/4D: ~6 Kg Dolphin/IQ: ~2 Kg Dolphin/MAX:~ 6 Kg	Dolphin/4D: ~6 Kg Dolphin/IQ: ~2 Kg Dolphin/MAX:~ 6 Kg	Identical to Dolphin predicate device
Dimensions (cm)	Dolphin/4D: 47x30x7 Dolphin/MAX: 47x30x7 Dolphin/IQ: 26.5x20.5x5.5	Dolphin/4D: 47x30x7 Dolphin/MAX: 47x30x7 Dolphin/IQ: 26.5x20.5x5.5	Identical to Dolphin predicate device
Frequency modes / Transducers	1.6MHz PW 2MHz PW	1.6MHz PW 2MHz PW	Identical to Dolphin predicate device

Specification	Dolphin devices [4D, IQ and MAX] with Dolphin/XF Robot accessory	Dolphin devices [4D, IQ and MAX] / EMS9UA with Roboprobe Headband [Predicate devices]	Differences discussion
(MHz)	4MHz PW/CW 8MHz PW/CW	4MHz PW/CW 8MHz PW/CW	
Patient surface contact materials	Compatible	Compatible	Identical to Dolphin predicate device
2 MHz Monitoring Probe	available	available	Identical to Dolphin predicate device
Monitoring headset	available	available	Identical to Dolphin predicate device
User controls	Remote control, foot switch, touch screen, key board, mouse	Remote control, foot switch, touch screen, key board, mouse	Identical to Dolphin predicate device
Display modes	Unilateral, bilateral, monitoring, external channels, HITS	Unilateral, bilateral, monitoring, external channels, HITS	Identical to Dolphin predicate device
Sample Volume (2 MHz)	1-20 mm	1-20 mm	Identical to Dolphin predicate device
Scale (2 MHz)	Up to 32 KHz depth dependent	Up to 32 KHz depth dependent	Identical to Dolphin predicate device
Power control	0-100 % of maximal derated I_{spta} within FDA guidelines	0-100 % of maximal derated I_{spta} within FDA guidelines	Identical to Dolphin predicate device
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 to Dolphin predicate device
M-mode display	available	available	Identical to Dolphin predicate device
Multi-gate windows	Up to 8	Up to 8	Identical to Dolphin predicate device
HITS detection	Available	Available	Identical to Dolphin predicate device
Velocity profile display	Available	Available	Identical to Dolphin predicate device
Cursors	Available	Available	Identical to Dolphin predicate device
Audio replay	Available	Available	Identical to Dolphin predicate device
Sweep time display	Up to 3 minutes	Up to 3 minutes	Identical to Dolphin predicate device
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 to Dolphin predicate device
Measurement accuracy	± 10% accuracy	± 10% accuracy	Identical to Dolphin predicate device

Specification	Dolphin devices [4D, IQ and MAX] with Dolphin/XF Robot accessory	Dolphin devices [4D, IQ and MAX] / EMS9UA with Roboprobe Headband [Predicate devices]	Differences discussion
accessories	Remote control, foot switch, monitoring head set, External Channels connection box, Wired remote control , Dolphin/XF Robot	Remote control, foot switch, monitoring head set, External Channels connection box, Wired remote control	Equivalent. The added accessory similar to EMS9UA predicate device
Velocity units	Cm/sec or KHz	Cm/sec or KHz	Identical to Dolphin predicate device
Summary screens	available	available	Identical to Dolphin predicate device
Patient database	available	available	Identical to Dolphin predicate device
Patient search options	available	available	Identical to Dolphin predicate device
Spectrum color palette selection	available	available	Identical to Dolphin predicate device
Insonation angle	User defined	User defined	Identical to Dolphin predicate device
Database backup options	available	available	Identical to Dolphin predicate device
Database statistics	available	available	Identical to Dolphin predicate device
Export	Multiple formats	Multiple formats	Identical to Dolphin predicate device
Analog input channels	8	8	Identical to Dolphin predicate device
Analog output channels	4	4	Identical to Dolphin predicate device
Configurable protocols	available	available	Identical to Dolphin predicate device
Specialty tests	available	available	Identical to Dolphin predicate device
Connectivity to PACS systems	available	available	Identical to Dolphin predicate device
Printer support	available	available	Identical to Dolphin predicate device
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 to Dolphin predicate device
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 External 15VDC, 9.6A or internal battery	Identical to Dolphin predicate device
Battery Operating Time	At least 3 hours of routine examination [applicable only to Dolphin/MAX]	At least 3 hours of routine examination [applicable only to Dolphin/MAX]	Identical to Dolphin predicate device
XF/Dolphin Robot Specifications:			
Clinical Application	Intracranial measurements	NA / Intracranial measurements	Identical to EMS9UA

Specification	Dolphin devices [4D, IQ and MAX] with Dolphin/XF Robot accessory	Dolphin devices [4D, IQ and MAX] / EMS9UA with Roboprobe Headband [Predicate devices]	Differences discussion
Weight (kg)	126 gr.	NA / 55 gr.	Both are very light, Dolphin/XF is slightly heavier which doesn't impact safety and clinical performance
Dimensions (cm)	8.5x7.5x3.5 cm	NA / 10.5x6x2 cm	Both have similar surface area. The Dolphin/XF slightly thicker which doesn't impact safety and clinical performance
Bilateral measurements	Yes	NA / Yes	Identical to EMS9UA
Option for Unilateral measurements	Yes	NA / Yes	Identical to EMS9UA
Probe Frequency used with the robot	2 MHz - same Doppler probe manufacturer	NA / 2MHz and 1 MHz - same Doppler probe manufacturer	The 2MHz monitoring probe is included with the EMS9UA reference device
Bilateral robot control	Separate control for each robot	NA / Separate control for each robot	Identical to EMS9UA reference device
Headset for robot	Dedicated bilateral headset. Allows to move the robot enclosure up/down and right/left and lock in place	NA / Robot headset. Allows to move the robot enclosure up/down and right/left and lock in place	Similar to EMS9UA Dolphin/XF headset is primarily made with flexible Velcro straps that allow tightening and loosening of the headset around the circumference of the head. The EMS9UA reference roboprobe headset is made from a combination of plastic parts and Velcro straps, whereas the tightening around the head is with a knob located in the region of the forehead. Both shares the same purpose.
Probe cover	A disposable biocompatible Cup in direct skin contact	Surrounding rubber ring around the probe	Similar to EMS9UA reference device. The Dolphin/XF Cup is biocompatible material complies with ISO10993-1.

Specification	Dolphin devices [4D, IQ and MAX] with Dolphin/XF Robot accessory	Dolphin devices [4D, IQ and MAX] / EMS9UA with Roboprobe Headband [Predicate devices]	Differences discussion
Search Axis	2	NA / 2	Identical to EMS9UA reference device
Signal search	Probe position is incrementally moved in 2 angular directions in a generally square grid pattern	NA / Probe position is incrementally moved in 2 angular directions in a generally square grid pattern	Similar to EMS9UA reference device
Grid matrix	16 x 16 points	NA / 9 x 9 points	The grid is similar. The Dolphin/XF has an improved resolution and further search points which doesn't impact product safety and performance
Search for signal	At each grid position, assessing for cerebral signal and signal intensity	NA / At each grid position, assessing for cerebral signal and signal intensity	Identical to EMS9UA reference device
Grid point coloring	Coloring each grid position with a color map of a range of red for flow towards the probe, range of blue for flow away from the probe, or no color if no signal detected	NA / Coloring each grid position with black for no signal detected, and then a range of colors from blue to yellow to green to orange to red based on signal quality	Similar to EMS9UA, the color codes used with the Dolphin/XF are in line with accepted m-mode color standards for towards and away flows
Search duration	Under 2 minutes	NA / Under 2 minutes	Identical to EMS9UA

5.5 UTILIZATION OF STANDARDS AND GUIDANCE'S:

The Dolphin/IQ, Dolphin/4D and Dolphin/MAX with Dolphin/XF robot accessory 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 with Dolphin/XF robot accessory 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 with the Dolphin/XF robot accessory are substantially equivalent to the predicate devices.