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

November 14, 2017

Re: K170859
Trade/Device Name: Dolphin/IQ and Dolphin/4D
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX
Dated: October 19, 2017
Received: October 23, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K170859

Device Name

Dolphin/IQ and Dolphin/4D

Indications for Use *(Describe)*

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

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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."*

# Indications For Use Form

System: Dolphin/IQ, Dolphin/4D

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
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
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
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
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

| | |
|---|---|
| Date: | 14-March-2017 |
| Submitter: | Viasonix Ltd.<br>10 Hamelacha Street<br>Raanana , ISRAEL 4366105<br>Phone : 972-9-7441692 |
| Official Correspondent: | Dan Manor, CEO |
| Trade Name: | Dolphin/IQ and Dolphin/4D |
| Classification Name: | Ultrasonic Pulsed Doppler Imaging System |
| Classification Number: | 21 CFR 892.1550 |
| Product Code: | IYN, ITX |
| Device Class: | Class II |
| Predicate Devices: | Primary:<br>Sonara and Sonara/Tek<br>VIASYS Healthcare, Inc,<br>510(k) Number – K060421<br><br>Secondary:<br>Doppler-Box<br>COMPUMEDICS GERMANY GMGH - DWL<br>510(k) Number - K051085 |

## 5.2 DEVICE DESCRIPTION

Dolphin/IQ and Dolphin/4D systems are part of the Dolphin product family of non-invasive peripheral vascular diagnostic systems. The Dolphin/IQ and the Dolphin/4D 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. The functionality and performance of both systems is identical. Both 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. Both support the same accessories: IR wireless remote control, foot switch and monitoring head set.
Wherever the term Dolphin is used in this document, it applies to the Dolphin/IQ and Dolphin/4D products. Otherwise, each product is specified specifically by name. The Dolphin systems 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 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.

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 and Dolphin/4D are similar to the predicate devices cited above 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 and Dolphin/4D devices are substantially equivalent to the predicate devices cited above.

### 5.4.1 Summary table of Comparison

| Specification | Dolphin/4D and Dolphin/IQ | Sonara and Sonara/tek | Doppler-Box | Differences discussion |
|---|---|---|---|---|
| 510(k) number | Proposed Device | K060421 | K051085 | NA |
| Manufacturer | VIASONIX LTD. | VIASYS HEALTHCARE, INC | COMPUMEDICS GERMANY GMGH - DWL | NA |
| Product regulation and code | 21 CFR 892.1550<br>Code: IYN, ITX | 21 CFR 892.1550<br>Code: IYN, ITX | 21 CFR 892.1550<br>Code: IYN, ITX | Identical to predicates |
| Indications for use | 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. | Sonara and Sonara/Tek systems are medical ultrasound Doppler devices for measuring the blood flow velocities in arteries and veins non-invasively. | The Doppler-Box is a medical ultrasound device for measuring the blood flow velocities in arteries and veins mainly subcutaneously. The 16MHz probe can also be used intraoperative. | Equivalent.<br><br>Intended use, use environment and target patient population is substantially equivalent to the predicate devices. The Dolphin devices don't include the 16MHz option for intraoperative use. |
| Clinical Applications | Intracranial<br>Extracranial<br>Peripheral | Intracranial<br>Extracranial<br>Peripheral | Intracranial<br>Extracranial<br>Peripheral<br>Intraoperative | Identical to Sonara and Sonara/tek |
| Weight (kg) | Dolphin/4D: ~6 Kg<br>Dolphin/IQ: ~2 Kg | Sonara: 10 Kg<br>Sonara/tek: 2 Kg | 1.5 Kg | -Dolphin/4D and the predicate, Sonara have an integrated computer and display.<br>-Dolphin/IQ and the predicate, Sonara/tek to be connected externally to PC and monitor. |
| Dimensions (cm) | Dolphin/4D: 47x30x7<br>Dolphin/IQ: 26.5x20.5x5.5 | Sonara: 39x30x26<br>Sonara/tek: 26.5x22x4 | 27x10.5x9 | -Dolphin/4D and the predicate, Sonara have an integrated computer and display.<br>-Dolphin/IQ and the predicate, Sonara/tek to be connected externally to PC and monitor. |
| Frequency modes / Transducers (MHz) | 1.6MHz PW<br>2MHz PW<br>4MHz PW/CW<br>8MHz PW/CW | 2MHz PW<br>4MHz PW/CW<br>8MHz PW/CW | 1MHz PW<br>2MHz PW<br>4MHz PW/CW<br>8MHz PW/CW<br>16MHz PW | The Dolphin 1.6MHz PW doesn't adversely impact the substantial equivalent to the predicate, the Doppler-Box. |
| Patient surface contact materials | Compatible | compatible | compatible | Patient surface contact probes materials are identical to all predicate devices from the same material/assembly manufacturer |
| 2 MHz Monitoring Probe | available | available | available | Identical to the predicate Sonara device |
| Monitoring headset | available | available | available | Similar to the predicate devices. All have same look, function and probe handling. |
| User controls | Remote control, foot switch, touch screen, key board, mouse | Remote control, foot switch, touch screen, key board, mouse | Remote control, foot switch, touch screen, key board, mouse | Identical to the predicate devices |
| Display modes | Unilateral, bilateral, monitoring, external channels, HITS | Unilateral, bilateral, monitoring,<br>HITS | Unilateral, bilateral, monitoring, external channels, HITS | Identical to Doppler-Box |

| Specification | Dolphin/4D and Dolphin/IQ | Sonara and Sonara/tek | Doppler-Box | Differences discussion |
|---|---|---|---|---|
| Sample Volume (2 MHz) | 1-20 mm | 1-20 mm | Available, range unknown | Identical to Sonara and Sonara/tek |
| Scale (2 MHz) | Up to 32 KHz depth dependent | Up to 16 KHz depth dependent | Up to 32 KHz depth dependent | Identical to Doppler-Box |
| Power control | 0-100 % of maximal derated $I_{spta}$ within FDA guidelines | 0-100 % of maximal derated $I_{spta}$ within FDA guidelines | 0-100 % of maximal derated $I_{spta}$ within FDA guidelines | Identical to the predicate devices |
| Maximal Acoustic $I_{spta.3}$ ($mW/cm^2$) | Below maximal FDA guideline limits<br><br>Comply with FDA limits:<br>$I_{spta.3} \leq 720$ $mW/cm^2$<br>MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 $W/cm^2$. | Below maximal FDA guideline limits<br><br>Comply with FDA limits:<br>$I_{spta.3} \leq 720$ $mW/cm^2$<br>MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 $W/cm^2$ | Below maximal FDA guideline limits<br><br>Comply with FDA limits:<br>$I_{spta.3} \leq 720$ $mW/cm^2$<br>MI ≤ 1.9 or the global maximum derated ISPPA ≤ 190 $W/cm^2$ | Equivalent to predicate devices |
| M-mode display | available | available | available | Identical to the predicate devices |
| Multi-gate windows | Up to 8 | Up to 8 | Available, # not known | Identical to Sonara and Sonara/tek |
| HITS detection | Available | Available | Available | Similar to predicate devices |
| Velocity profile display | Available | Available | Not available | Similar to Sonara and Sonara/tek |
| Cursors | Available | Available | Available | Identical to the predicate devices |
| Audio replay | Available | Available | Available | Identical to the predicate devices |
| Sweep time display | Up to 3 minutes | Up to 2 minutes | Available, sweep time not known | The sweep time display is only a display option with no impact on intended use |
| 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, heart rate | Peak velocity, mean velocity, end diastolic velocity, pulsatility Index, resistance index, systolic to diastolic ratio, rise time, heart rate | Identical to the predicate devices |
| Measurement accuracy | ± 10% accuracy | ± 10% accuracy | ± 10% accuracy | Identical to the predicate devices |
| accessories | Remote control, foot switch, monitoring head set | Remote control, foot switch, monitoring head set | Remote control, foot switch, monitoring head set | Equivalent |
| Velocity units | Cm/sec or KHz | Cm/sec or KHz | Cm/sec or KHz | Identical to the predicate devices |
| Summary screens | available | available | available | Identical to the predicate devices |
| Patient database | available | available | available | Identical to the predicate devices |
| Patient search options | available | available | available | Identical to the predicate devices |
| Spectrum color palette selection | available | available | Not available | Identical to Sonara and Sonara/tek |
| Insonation angle | User defined | User defined | User defined | Identical to the predicate devices |
| Database backup options | available | available | available | Identical to the predicate devices |
| Database statistics | available | available | Not available | Identical to Sonara and Sonara/tek |
| Export | Multiple formats | Multiple formats | Multiple formats | Identical to the predicate devices |
| Analog input channels | 8 | Not available | 8 | Identical to Doppler-Box |
| Analog output channels | 4 | Not available | 4 | Identical to Doppler-Box |
| Configurable protocols | available | available | available | Identical to the predicate devices |
| Specialty tests | available | available | available | Identical to the predicate devices |
| Connectivity to PACS systems | available | available | available | Identical to the predicate devices |
| Printer support | available | available | available | Identical to the predicate devices |
| Standards Compliance | IEC 60601-1 , 3.1 Ed.<br>IEC 60601-1-2. 4 Ed.<br>IEC 60601-2-37. 2.1 Ed. | IEC 60601-1 , 3.0 Ed.<br>IEC 60601-1-2. 3 Ed.<br>IEC 60601-2-37. 2.0 Ed. | IEC 60601-1 , 3.0 Ed.<br>IEC 60601-1-2. 2.0 Ed.<br>IEC 60601-2-37. 2.0 Ed. | Dolphin/4D and Dolphin/IQ complies with the most recent standards editions |

## 5.5 UTILIZATION OF STANDARDS AND GUIDANCE'S:

The Dolphin/IQ and Dolphin/4D 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

## 5.6 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Summary of Non-Clinical Tests:

The Dolphin/IQ and Dolphin/4D devices have been thoroughly tested through verification of specifications and validation, including software validation. The following performance verification testing were applied to the development of the system: Acoustic output Measurement, temperature rise and velocity accuracy testing.

## 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 and Dolphin/4D are substantially equivalent to the predicate devices.