Dolphin Medical Imaging, LLC
% Mr. Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

November 19, 2019

Re: K192573
Trade/Device Name: Dolphin Medical Imaging USB Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: November 8, 2019
Received: November 12, 2019

Dear Ms. Bom:

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,

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)*
K192573

Device Name
Dolphin Medical Imaging USB Ultrasound System

Indications for Use *(Describe)*
The Dolphin Medical Imaging USB Ultrasound System is intended for diagnostic ultrasound imaging in B mode. It is indicated for diagnostic ultrasound imaging in the following applications:

- Fetal/Obstetric
- Abdominal Pediatric
- Small Organ
- Musculo-skeletal (conventional)
- Musculo-skeletal (superficial)
- Urology
- Gynecology
- Pelvic Floor
- Neuro-muscular
- Peripheral Vessel

The system is intended for use by trained registered nurses and other trained healthcare professionals in a professional healthcare environment.

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

Provided in accordance with 21CFR 807.92 (c).

Submitter Information – 21 CFR 807.92 (a)(1)

Date of submission:	November 18, 2019
Submitter information:	Dolphin Medical Imaging, LLC 161 Dawn River Folsom, CA 95630
Contact Person:	Brian Heaney Chief Executive Officer Dolphin Medical Imaging 161 Dawn River Way Folsom, CA 95630 919.450.7668 brian.heaney@dolphinmedicalimaging.com

Name of Device and Classification – 21 CFR 807.92 (a)(2)

Device trade name:	Dolphin Medical Imaging USB Ultrasound System
Model number:	DMI-USB-001
Common name:	Diagnostic ultrasound system and transducers
Classification:	Class II

21 CFR Section	Classification Name	Product Code
892.1560	System, Imaging, Pulsed Echo, Ultrasonic	IYO
892.1570	Transducer, Ultrasonic, Diagnostic	ITX

Acoustic Output Limits Track

Track 3

Predicate Device - 21 CFR 807.92 (a)(2)

Interson USB Ultrasound System	K163443	4/13/2017

Device Description – 21 CFR 807.92 (a)(4)

The Dolphin Medical Imaging Ultrasound System ("DMI US") is a self-contained, solid-state portable ultrasound imaging system, physically comprised of the FDA-cleared Interson SP-L01 USB ultrasound probe (K163443), which is used in connection with the DMI US application software. The system contains an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface, B-mode imaging and application software providing the user interface.

The DMI US application software provides a task-oriented graphical user interface that runs on a personal computer with a USB 2.0 (or greater) port and the Windows 10 operating system. The user-selectable tasks supported are peripheral intravenous access and central venous access. The software application displays the ultrasound B-mode image at a depth appropriate for the selected task.

The initial operational settings of the probe and/or application are preprogrammed in the system. User-customized parameter settings for each probe and/or application may be set by the operator and stored for recall as needed via the software user interface. Customization includes changing image brightness (gain), changing depth and freezing/unfreezing the ultrasound image. The system uses a probe with solid-state ultrasound array transducers which provide high resolution, high penetration performance

Intended Use/Indications for Use – 21 CFR 807.92 (a)(5)

The Dolphin Medical Imaging USB Ultrasound System is intended for diagnostic ultrasound imaging in B mode. It is indicated for diagnostic ultrasound imaging in the following applications:

- Fetal/Obstetric
- Abdominal Pediatric
- Small Organ
- Musculo-skeletal (conventional)
- Musculo-skeletal (superficial)
- Urology
- Gynecology
- Pelvic Floor
- Neuro-muscular
- Peripheral Vessel

The system is intended for use by trained registered nurses and other trained healthcare professionals in a professional healthcare environment.

Summary of technological characteristics of the device compared to the predicate device – 21 CFR 807.92 (a)(6)

Device Features	Subject Device: DMI USB Ultrasound System	Predicate Device: Interson Ultrasound System K164443
Intended Use	Diagnostic ultrasound imaging in B mode.	Diagnostic ultrasound imaging in B, color Doppler and Combined (B+Color) mode.
Indications for Use	Indicated for diagnostic ultrasound imaging in specified applications.	Indicated for diagnostic ultrasound imaging in specified applications.
Product Code	IYO, ITX	IYN, IYO, ITX
Array Geometry	Linear	Curved and linear
Mechanics	Solid State	Solid State
Software platform	Commercial off-the-shelf operating system (Windows)	Commercial off-the-shelf operating system (Windows)
Measurement function	Not supported	2D measurement and area measurement
Wireless networking	Not supported	Not supported
Connector	USB	USB

Determination of Substantial Equivalence

The Dolphin Medical Imaging USB Ultrasound System hardware is identical to the predicate device. The Dolphin Medical Imaging USB Ultrasound System application software provides a subset of the predicate device application software.

Non-clinical Performance Data

Non-clinical testing relied on in this premarket notification submission for a determination of substantial equivalence include tests which show compliance with the following standards.

NOTE: Testing per ES60601-1:2005; and IEC 60601-1-2:2014 was performed for use of the transducer with a specific computer model (Dell T15G) while internally powered and not connected to mains. Use of alternate USB 2.0 compatible computer hardware requires verification by the end user. Further information is provided in the Instructions for Use.

1. Recognition Number 12-105: NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3. (Radiology)
2. Recognition Number 19-4: AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
3. Recognition Number 12-293: IEC 60601-2-37 (2015), Amendment 2, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. (Radiology)
4. Recognition Number 19-8: IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

5. Recognition Number 5-89: IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6. Recognition Number 5-40: ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices
7. Recognition Number 2-173: AAMI ANSI ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
8. Recognition Number 2-153: AAMI ANSI ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Summary of Clinical Tests

The Dolphin Medical Imaging USB Ultrasound System introduces no new modes, features, or technologies relative to the predicate device (Interson K163443) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

514 Performance Standards

There are no Sec. 514 performance standards for this device.

Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Site(s)

Not applicable. No components are supplied sterile.

Conclusions

Dolphin Medical Imaging concludes that the subject device, the Dolphin Medical Imaging USB Ultrasound System, has been shown to be substantially equivalent to the predicate device identified above.