DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2017

Butterfly Network, Inc.
% Mr. Brian Sawin
Sr. Regulatory Affairs Manager
530 Old Whitfield Street
GUILFORD CT 06437

Re: K163510
Trade/Device Name: Poseidon Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 9, 2017
Received: August 10, 2017

Dear Mr. Sawin:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert A. 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)*
K163510

Device Name
Poseidon Ultrasound System

Indications for Use *(Describe)*
The Poseidon Ultrasound System is indicated for use by qualified and trained healthcare professionals to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid and arterial studies), Procedural Guidance, Small Organs (including thyroid), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional) and Musculoskeletal (superficial).

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.

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Diagnostic Ultrasound Indications For Use Table

System: Poseidon Ultrasound System

Transducer: Poseidon Ultrasound System transducer

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							
Fetal Imaging & Other	Fetal/Obstetric	N	N			N	B mode + M mode	
	Abdominal	N	N			N	B mode + M mode	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N			N	B mode + M mode	
	Small Organ (including thyroid)	N	N			N	B mode + M mode	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Superficial)	N	N			N	B mode + M mode	
	Intravascular							
	Other (Musculo-skeletal - Conventional)	N	N			N	B mode + M mode	

	Other (Gynecological)	N	N			N	B mode + M mode	
	Other (Urology)	N	N			N	B mode + M mode	
	Other (Specify)							
Cardiac	Cardiac Adult	N	N			N	B mode + M mode	
	Cardiac Pediatric	N	N			N	B mode + M mode	
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N			N	B mode + M mode	
	Other (Carotid, arterial studies)	N	N			N	B mode + M mode	
	Other (Procedural Guidance)	N	N			N	B mode + M mode	

N = new indication; P = previously cleared by FDA; E = added under this appendix

510(k) Summary of Safety and Effectiveness

Submitter Information

Submitter Name and Address

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Contact Person

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Date Prepared

August 9, 2017

Subject Device - Proprietary/Trade Name

Poseidon Ultrasound System

Subject Device - Common Name

Ultrasound Imaging System

Classification Name

	Regulation Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Classification

Class II

Predicate Device:

K162549 – Philips Healthcare, Lumify Ultrasound System (Clearance Date:

10/03/2016)

Device Summary:
The Poseidon Ultrasound System is a general-purpose diagnostic imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid on adult and pediatric patients. The system consists of a single transducer with broad imaging capabilities connected via a USB cable to a standard handheld commercial off the shelf (COTS) mobile device. In addition to M-mode and B-mode imaging the instrument also supports Color Flow Doppler imaging.

The user interface includes touchscreen menus, buttons, controls, indicators and navigation icons that allow the operator to control the system and to view and measure ultrasound imagery.

Indications for Use:
The Poseidon Ultrasound System is indicated for use by qualified and trained healthcare professionals to enable diagnostic ultrasound imaging and measurement of anatomical structures and fluids of adult and pediatric patients for the following clinical applications: Peripheral Vessel (including carotid and arterial studies), Procedural Guidance, Small Organs (including thyroid), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional) and Musculoskeletal (superficial).

Summary of Technological Characteristics
There are no technological characteristics, features or indications for use in this submission that are not previously evaluated and cleared in the predicate device, with the exception of utilizing a capacitive micromachined ultrasonic transducer (CMUT) array rather than a traditional crystalline piezoelectric array. This technology meets the same intended use and performs the same actions as piezoelectric material.

Summary of Safety and Performance
Verification and validation activities were designed and performed to demonstrate that the Poseidon Ultrasound System meets predetermined performance specifications. The following standards were used to determine appropriate methods for evaluating the performance of the device:

IEC 60601-1: *Medical Electrical Equipment – Part 1: General Requirements for Safety.*

IEC 60601-1-2: *Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*.

IEC 60601-2-37: *Medical Electrical Equipment – Part 2-37: Particular*

Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment.

ISO 10993:2009 *Biological Evaluation of Medical Devices. Part 1*

NEMA UD-2: *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.*

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics, and safety and performance testing, the subject device meets the requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate device.