Butterfly Network, Inc.
% Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

September 16, 2020

Re: K202406
Trade/Device Name: Butterfly iQ 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 18, 2020
Received: August 21, 2020

Dear Prithul 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)*
K202406

Device Name
Butterfly iQ Ultrasound System

Indications for Use *(Describe)*

The Butterfly iQ Ultrasound System is indicated for use by trained healthcare professionals in environments where healthcare is provided 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, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and Ophthalmic. Modes of operation include B- mode, B-mode + M-mode, B-mode + Color Doppler, B-mode + Power Doppler.

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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K202406

510(k) Summary or Statement

530 Old Whitfield Street
Guilford, CT 06437
(203) 458-7100

510(k) Summary of Safety and Effectiveness

Submitter Information

Submitter Name and Address

Butterfly Network, Inc.
530 Old Whitfield St.
Guilford, CT 06437 USA
(tel.) 855-296-6188
(fax) 203-458-2514
www.butterflynetwork.com

Contact Person

Brian Sawin
Sr. Regulatory Affairs Manager
855-296-6188
bsawin@butterflynetwork.com

Date Prepared

July 20, 2020

Subject Device - Proprietary/Trade Name

Butterfly iQ 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:

K163510 – Poseidon Ultrasound System, Butterfly Network, Inc.
(Clearance Date: 09/06/2017)

K170714 – Venue, GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
(Clearance Date: 06/22/2017)

Device Summary:

The Butterfly iQ Ultrasound System is a general-purpose diagnostic imaging system for use by qualified and trained healthcare professionals in environments where healthcare is provided to enable visualization and measurement of anatomical structures and fluid of adult and pediatric patients. The system consists of a single transducer with broad imaging capabilities connected 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 Doppler and Power 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 Butterfly iQ Ultrasound System is indicated for use by trained healthcare professionals in environments where healthcare is provided 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, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and Ophthalmic. Modes of operation include B-mode, B-mode + M-mode, B-mode + Color Doppler, B-mode + Power Doppler.

Summary of Technological Characteristics

The Butterfly iQ Ultrasound System has a substantially equivalent intended use, imaging capability, technological characteristics and safety and effectiveness as the legally marketed predicate device and is used to aid in diagnosis. The subject and predicate devices are based on the following substantially equivalent clinical and technological elements:

- Diagnostic ultrasound system
- Ophthalmic clinical application

The following clinical and technological differences exist between the subject and predicate:

- Transrectal, Transvaginal, Neonatal and adult cephalic, Thoracic/pleural and Cardiac Fetal Echo clinical applications
- Handheld vs. mobile
- Single probe vs. multiple

- Commercial off the shelf display vs. LCD display

Device Comparison Table:

	Butterfly iQ Ultrasound System (This submission)	**Butterfly Poseidon Ultrasound System 510(k): K163510**	**Venue 510(k): K170714**
FDA Clearance			
	No - original submission	Yes (September 6, 2017)	Yes (June 22, 2017)
Intended Use			
	Intended for use by trained healthcare professionals in environments where healthcare is provided 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, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional), Musculoskeletal (superficial) and Ophthalmic. Modes of operation include B-mode, B-mode + M-mode, B-mode + Color Doppler, B-mode + Power Doppler.	Intended 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, deep vein thrombosis and arterial studies), Procedural Guidance, Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Urology, Fetal/Obstetric, Gynecological, Musculoskeletal (conventional) and Musculoskeletal (superficial).	Intended for ultrasound imaging, measurement and analysis of the human body and fluid for multiple clinical applications including: abdominal (GYN and Urology), thoracic/pleural, ophthalmic, Fetal/OB, Small Organ (including breast, testes, thyroid), Peripheral vascular, neonatal and adult cephalic, pediatric, musculoskeletal (conventional and superficial), cardiac (adults and pediatric), Transrectal, Transvaginal, and imaging guidance of interventional procedures (e.g. Nerve block, vascular access).
General Device Description			
	Hand held portable diagnostic ultrasound system.	Hand held portable diagnostic ultrasound system.	Mobile diagnostic ultrasound system.
Clinical Applications			

	Ophthalmic	Not Applicable	Ophthalmic
	Abdominal	Abdominal	Abdominal
	Cardiac	Cardiac	Cardiac
	Carotid	Carotid	Carotid
	Musculo-skeletal (conventional and superficial)	Musculo-skeletal (conventional and superficial)	Musculo-skeletal (conventional and superficial)
	Fetal/Obstetric, Gynecological	Fetal/Obstetric, Gynecological	Fetal/Gynecological
	Peripheral Vessel (including carotid, deep vein thrombosis, arterial studies)	Peripheral Vessel (including carotid, deep vein thrombosis, arterial studies)	Peripheral Vessel
	Procedural Guidance	Procedural Guidance	Imaging guidance of interventional procedures
	Small Organs including thyroid, scrotum, and breast	Small Organs including thyroid, scrotum, and breast	Small Organs including thyroid, scrotum, and breast
	Urology	Urology	Urology
	Not Applicable	Not Applicable	Transrectal
	Not Applicable	Not Applicable	Transvaginal
	Not Applicable	Not Applicable	Neonatal and adult cephalic
	Not Applicable	Not Applicable	Thoracic/pleural
	Not Applicable	Not Applicable	Cardiac Fetal Echo
Relevant Similarities			
Target Population	Fetal, Pediatric, Adult, Male, Female	Fetal, Pediatric, Adult, Male, Female	Fetal, Pediatric, Adult, Male, Female
Where used	Professional healthcare settings	Professional healthcare settings	Environments where healthcare is provided by healthcare professionals
Energy used/delivered (MI/TI)	Meets FDA/AIUM guidelines	Meets FDA/AIUM guidelines	Meets FDA/AIUM guidelines
FDA Regulatory Classification	Class II	Class II	Class II
510(k) Track	Track 3	Track 3	Track 3

Portable/hand-held	Yes	Yes	Yes
Biocompatibility	Yes	Yes	Yes
Sterility	Products not classified as sterile	Products not classified as sterile	Products not classified as sterile
Electrical safety	Meets electrical safety standards for a class II medical device.	Meets electrical safety standards for a class II medical device.	Meets electrical safety standards for a class II medical device.
Mechanical safety	Meets mechanical safety standards for a class II medical device	Meets mechanical safety standards for a class II medical device	Meets mechanical safety standards for a class II medical device
FDA Product Codes	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX
Transducer			
Type	Single probe 2D Phased Array	Single probe 2D Phased Array	Multiple probes including, convex, linear and phased Array
Pan/Zoom			
Real-time image	Yes	Yes	Yes
Frozen image	Yes	Yes	Yes
Miscellaneous			
Display	COTS device display	COTS device display	LCD device display
Scan time	Battery (120 minutes continuous scan time)	Battery (120 minutes continuous scan time)	Battery (240 minutes continuous scan time)

Summary of Safety and Performance

Verification and validation activities were designed and performed to demonstrate that the Butterfly iQ Ultrasound System meets predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

IEC 60601-1:Edition 3.0 – 2005 (3.0 2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012). Medical Electrical Equipment – Part 1: General *Requirements for Safety.*

IEC 60601-1-2:Edition 4.0 - 2014, *Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*.

IEC 60601-2-37:Edition 2.0 Am 1 – 2015, 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: 2004 Rev 3, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

Summary of Substantial Equivalence:
The Butterfly iQ Ultrasound System is as safe and effective as the predicate has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences raise no new issues of safety or effectiveness. Performance data, including software verification and validation and performance testing demonstrate that the Butterfly iQ Ultrasound System is safe and effective and therefore, substantially equivalent.