January 4, 2024

Butterfly Network, Inc.
% Nathan Sabich
Senior Director, Head of Global Regulatory Affairs
1600 District Ave
BURLINGTON MA 01803

Re: K232808
Trade/Device Name: Butterfly iQ3 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: December 1, 2023
Received: December 4, 2023

Dear Nathan Sabich:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232808

Device Name

Butterfly iQ3 Ultrasound System

Indications for Use *(Describe)*

The iQ3 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, deep vein thrombosis and arterial studies), Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Lung, Procedural Guidance, 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, Spectral Pulsed Wave Doppler, Fetal Heart Sounds, B-mode + Biplane, B-mode + Needle Viz Tool, B-mode + Biplane + Needle Viz Tool, B-mode + Multi-Slice, and B-mode + Sweep.

The Butterfly iQ3 Ultrasound System's portability and user interface enables integration into professional healthcare facilities (e.g. Hospital, clinic, hospice, or medical office), home healthcare environment, ambulances and/or accident sites, and other environments where healthcare is provided. Users may also include medical students working under the supervision or authority of a physician during their education/training.

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 of Safety and Effectiveness
Butterfly Network, Inc.

K232808

This 510(k) summary is submitted in accordance with 21 CFR Part 807.92:

Date Prepared: September 8, 2023

Submitter Name and Address:
Butterfly Network, Inc.
1600 District Ave
Burlington, MA 01803
Phone: 1-781-557-4800

Primary Contact:
Nathan Sabich
Senior Director, Head of Global Regulatory Affairs
E-mail: nsabich@butterflynetinc.com

Subject Device - Proprietary/Trade Name:
Butterfly iQ3 Ultrasound System

Subject Device – Common/Usual Name:
Diagnostic Ultrasound Imaging System

Device Classification:
Class II

Regulation Description:

Classification Name(s)	Regulation Number	Product Code
Primary		
Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550	IYN
Secondary		
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasound Transducer	21 CFR 892.1570	ITX
Medical Image Management and Processing System	21 CFR 892.2050	QIH

Predicate Device Information:

Device Trade Name:	Butterfly iQ/iQ+ Ultrasound System
510(k) Number:	K220068
Submitter:	Butterfly Network, Inc.
Classification Name:	Ultrasonic Pulsed Doppler Imaging System
Primary Product Code:	IYN – 21 CFR 892.1550
Secondary Product Code(s):	IYO – 21 CFR 892.1560 ITX – 21 CFR 892.1570 QIH – 21 CFR 892.2050

Note: The predicate device has not been subject to a design-related recall.

Device Description:

The Butterfly iQ3 Ultrasound System is a portable, hand-held, 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 touch screen 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 iQ3 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, deep vein thrombosis and arterial studies), Small Organs (including thyroid, scrotum and breast), Cardiac, Abdominal, Lung, Procedural Guidance, 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, Spectral Pulsed Wave Doppler, Fetal Heart Sounds, B-mode + Biplane, B mode + Needle Viz Tool, B-mode + Biplane + Needle Viz Tool, B-mode + Multi-Slice, B-mode + Sweep.

The Butterfly iQ3 Ultrasound System's portability and user interface enables integration into professional healthcare facilities (e.g. Hospital, clinic, hospice, or medical office), home healthcare environment, ambulances and/or accident sites, and other environments where healthcare is provided. Users may also include medical students working under the supervision or authority of a physician during their education/training.

Summary of Technological Characteristics:
There are no technological characteristics and features that change the indications for use in this submission that are not previously evaluated and cleared in the predicate device. The iQ3 represents a new Butterfly iQ App compatible transducer.

As with the iQ and iQ+, the iQ3 uses a capacitive micromachined ultrasonic transducer (CMUT) array rather than a traditional crystalline piezoelectric array. The system remains battery operated and all image interaction and capture is with the existing iOS and Android host applications. The Bladder Volume and B-lines tools remain compatible with the images generated with the iQ3.

As with the iQ+, the iQ3 includes new printed circuit board assemblies and a next generation release of the CMUT array. Additionally, the iQ3 uses a new custom battery, a new lens material (butadiene synthetic rubber), and replaces the induction coil charging method with a direct contact charging system.

Summary of Safety and Non-Clinical Performance:
The Butterfly iQ3 Ultrasound System was developed and tested in accordance with internal procedures for safety, design quality, and documentation.

Verification and validation activities were designed and performed to demonstrate that the Butterfly iQ3 Ultrasound System meets predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the safe and effective performance of the device:

IEC 60601-1 Ed. 3.2 en: 2020	Medical Electrical Equipment – Part 1. General requirements for basic safety and essential performance
IEC 60601-1-11 Ed. 2.1 b:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment CONSOLIDATED EDITION
IEC 60601-1-12 Ed. 1.1 b:2020	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment CONSOLIDATED EDITION
IEC 60601-1-2: 2014/AMD1:2020	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-2-37 Ed. 2.0 b: 2007	Medical Electrical Equipment – Part 2-37. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment CONSOLIDATED EDITION
ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 14971:2019	Application of risk management to medical devices

Software Verification and Validation Testing for the Butterfly iQ3 Ultrasound System was also conducted and provided in accordance with recommended FDA guidance documentation for Industry and FDA Staff.

Relevant non-clinical verification and validation testing was performed to address the introduction of the subject hardware and its compatibility with the cleared Butterfly iQ App and to assure its safe and effective performance. Verification and validation testing established that the device meets its design requirements, intended use, and demonstrates substantial equivalence to the predicate.

Summary of Clinical Tests:
The Butterfly iQ3 Ultrasound System did not require clinical studies to support substantial equivalence for this premarket submission.

Summary of Substantial Equivalence:

The Butterfly iQ3 Ultrasound System is substantially equivalent to the predicate device (K220068). The following table below provides an overview of the comparison between the subject device and the predicate device.

Model	**Butterfly iQ3 Ultrasound System (Subject Device)**	**Butterfly iQ/iQ+ Ultrasound System (K220068, Predicate Device)**	**Comparison**
Regulatory Information			
Regulation Number	892.1550	892.1550	Remains Unchanged

Device Classification Name	Ultrasonic Pulsed Doppler Imaging System	Ultrasonic Pulsed Doppler Imaging System	Remains Unchanged
Classification	Class II	Class II	Remains Unchanged
Product Codes	IYN IYO ITX QIH	IYN IYO ITX QIH	Remains Unchanged
Intended Use			
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.	✓	✓	Remains Unchanged
General Device Description			
Hand-held portable diagnostic ultrasound system.	✓	✓	Remains Unchanged
Indications for Use			
Abdominal	✓	✓	Remains Unchanged
Cardiac	✓	✓	Remains Unchanged
Lung	✓	✓	Remains Unchanged
Musculoskeletal (conventional and superficial)	✓	✓	Remains Unchanged
Fetal/Obstetric, Gynecological	✓	✓	Remains Unchanged

Peripheral Vessel (including carotid, deep vein thrombosis, arterial studies)	✓	✓	Remains Unchanged
Procedural Guidance	✓	✓	Remains Unchanged
Small Organs (including thyroid, scrotum, and breast)	✓	✓	Remains Unchanged
Urology	✓	✓	Remains Unchanged
Opthalmic	✓	✓	Remains Unchanged
Imaging Modes/Tools			
M-Mode	✓	✓	Remains Unchanged
B-Mode (2D)	✓	✓	Remains Unchanged
Color Doppler	✓	✓	Remains Unchanged
Pulsed Wave Doppler	✓	✓	Remains Unchanged
3-D	✓	✓	Remains Unchanged
Harmonic Imaging	✓	✓	Remains Unchanged
Fetal Heart Sounds	✓	✓	Remains Unchanged
B-mode + Biplane	✓	✓	Remains Unchanged
B-mode + Needle Viz Tool	✓	✓	Remains Unchanged

B-mode + Biplane + Needle Viz Tool	✓	✓	Remains Unchanged
B-mode + Multi-Slice	✓	-	Multi-slice collects and displays B-mode images from different angles separately. This new mode does not change the acoustic output to the normal B-Mode or 3-D image, nor does it introduce any new questions of safety and effectiveness.
B-mode + Sweep	✓	-	Sweep collects and continuously displays B-mode images from different angles. This new mode does not change the acoustic output to the normal B-Mode or 3-D image, nor does it introduce any new questions of safety and effectiveness.
Transducer			
Type	Single probe 2D Phased Array	Single probe 2D Phased Array	Remains Unchanged

Frequency	1.0 - 12 MHz	1.0 - 10 MHz	Similar. The subject device remains within the boundaries of the predicate device and does not introduce any new questions of safety and effectiveness.
Software Features			
Auto B-Lines Counter	✓	✓	Remains Unchanged
Auto Bladder Volume	✓	✓	Remains Unchanged
Patient Data Entry	✓	✓	Remains Unchanged
Patient Database and Storage	✓	✓	Remains Unchanged
Generic Measurement Tools	✓	✓	Remains Unchanged
Analysis and Calculation Packages	✓	✓	Remains Unchanged
Annotations	✓	✓	Remains Unchanged
Other			
Target Population	Adult and Pediatric	Adult and Pediatric	Remains Unchanged
Device Use Settings	Professional healthcare facilities (e.g. Hospital, clinic, hospice, or medical office),	Professional healthcare facilities (e.g. Hospital, clinic, hospice, or medical office), home healthcare	Remains Unchanged

	home healthcare environment, ambulances and/or accident sites, and other environments where healthcare is provided. Users may also include medical students working under the supervision or authority of a physician during their education/ training.	environment, ambulances and/or accident sites, and other environments where healthcare is provided. Users may also include medical students working under the supervision or authority of a physician during their education/ training.	
Energy used/delivered (MI/TI)	Acoustic will meet FDA/AIUM guidelines	Acoustic will meet FDA/AIUM guidelines	Remains Unchanged
Portable/hand-held	✓	✓	Remains Unchanged
Biocompatibility	✓	✓	Remains Unchanged
Sterility	Products not classified as sterile	Products not classified as sterile	Remains Unchanged
Cleaning/Reprocessing Methods	✓	✓	Remains Unchanged
Electrical safety	Meets electrical safety standards for a class II medical device. Group 1 Class B (CISPR)	Meets electrical safety standards for a class II medical device. Group 1 Class B (CISPR)	Remains Unchanged
Mechanical safety	Will meet mechanical safety standards for a class II medical device	Will meet mechanical safety standards for a class II medical device	Remains Unchanged
Display	COTS device display	COTS device display	Remains Unchanged

Power requirements	Battery	Battery	Remains Unchanged
Real-time Image	✓	✓	Remains Unchanged
Frozen Image	✓	✓	Remains Unchanged
Appx. Probe dimensions (L x W x D), inches	6.0 x 2.1 x 1.4	6.4 x 2.2 x 1.4	Change in size of probe
Appx. Probe Weight, lbs.	8 oz. probe only	8 oz. probe only	Remains Unchanged

Conclusion:
Based on the subject device's intended use, design similarities, technological characteristics, mode of operation, conformance to recognized performance standards, and relevant performance testing, the Butterfly iQ3 Ultrasound System does not introduce any new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device (K220068).