March 31, 2023

Butterfly Network, Inc.
℅ Lynda Ikejimba
Senior Regulatory Affairs Program Manager
1600 District Ave
BURLINGTON MA 01803

Re: K220068
Trade/Device Name: Butterfly iQ\ 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, QIH
Dated: March 6, 2023
Received: March 6, 2023

Dear Lynda Ikejimba:

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,

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.

510(k) Number *(if known)*
K220068

Device Name
Butterfly iQ/iQ+ Ultrasound System

Indications for Use *(Describe)*

The Butterfly iQ/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, Lung, 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.

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.

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."

Butterfly™
The New Image of Health

1600 District Ave
Burlington, MA 01803

(781) 557-4800

This 510(k) Summary is submitted in accordance with 21 CFR §807.92 K220068

I. SUBMITTER

Manufacturer:
Butterfly Network, Inc.
1600 District Ave
Burlington, MA 01803
Phone: 1-781-557-4800

Contact Person:
Lynda Ikejimba, PhD
Senior Regulatory Affairs Program Manager
E-mail: likejimba@butterflynetinc.com

Date Prepared: March 6, 2023

II. DEVICE

Trade Name: Butterfly iQ/ Butterfly iQ+ Ultrasound System
Common Name: Ultrasound Imaging System
Classification Name(s):
Ultrasonic Pulsed Doppler Imaging System (21 CFR 892.1550)
Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560)
Diagnostic Ultrasound Transducer (21 CFR 892.1570)
Automated Radiological Image Processing Software (21 CFR 892.2050)
Regulatory Class: II
Primary Product Code: IYN
Secondary Product Codes: IYO, ITX, QIH
Classification Panel: Radiology

III. PREDICATE DEVICE

Primary Predicate: Butterfly iQ Ultrasound System (K202406)
This predicate has not been subject to a design-related recall.

Reference Predicates: Philips Lumify Diagnostic Ultrasound System (K203406), GE Venue (K170714)

IV. DEVICE DESCRIPTION

The Butterfly iQ/Butterfly iQ+ Ultrasound System is a hand-held general-purpose diagnostic imaging system for use by 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 compatible with the Butterfly iQ/iQ+ mobile application (app).

The subject device introduces the Auto B-line Counter, a software application backed by an image analysis algorithm. The purpose of the Auto B-line Counter is to provide automated detection and automatic calculation of the number of B-lines to a user in a given rib space and also provides the users the capabilities of reviewing the detected B-lines (via visual overlays). The overlay of B-lines does not mark images for detection of specific pathologies. The Auto B-line Counter enables the automated identification and count of B-lines during a lung scan and is integrated into the existing Butterfly iQ/iQ+ mobile application for use with the Butterfly iQ or iQ+ transducers.

V. INDICATIONS FOR USE

The Butterfly iQ/Butterfly iQ+ Ultrasound System is indicated for use by a trained healthcare professional in an environment 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), 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device contains the same hardware technology as the previously cleared predicate device Butterfly iQ/iQ+ (K202406), and the subject device is compatible with both the Butterfly iQ and iQ+ Ultrasound systems. There is an addition of “lung” to the Indications For Use statement and Spectral Pulsed Wave Doppler to the modes of operation. These additions do not introduce any additional risks as there have been no changes in the other modes or compatible transducer frequencies and Spectral Pulsed Wave Doppler is a well-established mode of operation. The differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use as a general-purpose diagnostic ultrasound imaging system. A comparison of the proposed Butterfly iQ/Butterfly iQ+ Ultrasound System to the currently marketed predicate is provided in the table below.

Comparison Category	Butterfly iQ/iQ+ Ultrasound System (Subject Device)	Butterfly iQ Ultrasound System (Primary Predicate) (K202406)	Comparison
General Device Description	Hand held portable diagnostic ultrasound system	Hand held portable diagnostic ultrasound system	Remains Unchanged
Indications for Use	The Butterfly iQ/ 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, Lung, 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 +	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	Addition of “lung” to Indications for Use and Spectral Pulsed Wave Doppler to operating mode.

	Power Doppler, Spectral Pulsed Wave Doppler.	Doppler, B-mode + Power Doppler.	
Type	Single probe 2D phased array	Single probe 2D phased array	Remains Unchanged
Sterility	Non-sterile	Non-sterile	Remains Unchanged
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Remains Unchanged
Reusable	Yes	Yes	Remains Unchanged
Principles of Operation (subject Auto B-Line Counter)	Automatic detection and counting of B-lines from lung ultrasound images	Manual counting of B-lines from lung ultrasound images	Auto B-Line Counter added to existing Butterfly iQ/Butterfly iQ+ Ultrasound System App

VII. PERFORMANCE DATA

Performance Testing

Butterfly Network's iQ/iQ+ Ultrasound System was developed and tested in accordance with company design control processes and safety and performance testing. Relevant non-clinical verification and validation testing was performed to address the introduction of the subject software algorithm for the Auto B-Lines Counter and to assure its safe and effective performance.

Analytical Testing

Analytical Validation testing was performed to demonstrate that the Auto B-line Counter algorithm performance is non-inferior to clinician annotators (Ground Truth). The Auto B-line Counter met the acceptance criteria for all tests. Performance was assessed by the widely accepted metrics, the intraclass correlation coefficient (ICC) between annotators for the Quality Indicator and Dice Coefficient Score (DSC), for the conformance of automatic B-line segmentation to ground truth.

A validation dataset was curated by random selection of 6000 de-identified cines acquired from 253 sites. The datasets spanned many demographic variables including gender (male, female, and unidentified), age (20-90 years), and ethnicity via collection from a multitude of clinical sites with diverse and distinct racial patient populations.

<u>Clinical subgroups and confounders:</u>

The algorithm performance was verified on all demographic subgroups and clinical subgroups with various confounders present including but not limited to congestive heart failure, heart

failure reduced ejection fraction, diabetes with and without chronic complication, myocardial infarction, peripheral vascular disease, renal disease, and many other factors.

Truthing process:
The ground truthing for B-line counts was determined by the ICC among expert annotators presented with lung cines and instructions to determine the maximum number of B-Lines using the instant percent method. The ground truth locations of B-lines were then determined by expert annotator segmentations.

The data used for verification is completely distinct from that used during the training process and there is no overlap between the two. Independence of testing and training data was ensured by auditability–each study and associated images had unique dataset identification– and by sequestration–no study or its images could belong to multiple datasets.

Clinical Performance Evaluation
The clinical performance was evaluated on 99 subjects and demonstrated that the Auto B-line Counter algorithm performance is non-inferior to clinician annotator ground truth. Performance was assessed by calculating the intraclass correlation coefficient (ICC) between the tool and the ground truth. Additionally, the evaluation concluded that the algorithm's performance was consistent among clinically meaningful subgroups: age, gender, and BMI. Overall, the results support the generalizability of the Auto B-line Counter across the intended patient population.

Non-clinical Evaluation
The introduction of the Butterfly Auto B-Lines Counter was tested in accordance with internal Butterfly standards for safety and design quality and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered a "moderate" level of concern. The activities to ensure safe and effective performance of the subject software revision include but are not limited to Requirements Review, Risk Analysis and Management, Product Specifications, Design Reviews, Product Performance testing. Additional non-clinical evaluation demonstrated that the inclusion of the Auto B-Line Counter did not introduce any additional risks to the previously cleared Butterfly iQ/iQ+ Ultrasound System.

Summary
Based on the clinical performance as documented in the pivotal clinical study, the Butterfly Auto B-Lines Counter was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, 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 and does not raise new questions of safety or effectiveness to the predicate device. The subject device was found to have a safety and effectiveness profile that is similar to the predicate device.