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

June 11, 2020

Re: K200980
Trade/Device Name: Auto 3D Bladder Volume Tool
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: April 8, 2020
Received: April 14, 2020

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. 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)*
K200980

Device Name
Auto 3D Bladder Volume Tool

Indications for Use *(Describe)*
The Butterfly Auto 3D Bladder Volume Tool is a software application package. It is designed to view, quantify and report results acquired on Butterfly Network ultrasound systems for noninvasive volume measurements of the bladder, to support physician diagnosis. Indicated for use in adult populations.

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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510(k) Summary or Statement K200980

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

June 8, 2020

Subject Device - Proprietary/Trade Name

Auto 3D Bladder Volume Tool

Subject Device - Common Name

Diagnostic Ultrasound System with accessories

Classification Name

Classification Name	Regulation Number	Product Code
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasound Transducer	21 CFR 892.1570	ITX

Classification

Class II

Predicate Device:

K172356 – BladderScan Prime PLUS System, Verathon, Inc. (Clearance Date: 09/15/2017)

Device Summary:
The Butterfly Auto 3D Bladder Volume Tool is a software application used on Butterfly iQ Ultrasound Systems to provide a non-invasive measurement of bladder volume. The system calculates the bladder volume using proprietary artificial intelligence automatic segmentation and volume measurement algorithms on Butterfly Network ultrasound systems.

The Auto 3D Bladder Volume Tool allows the clinician to calculate bladder volume when using the Bladder preset in B-mode. The tool is used to acquire 25, 2D images of the bladder. Once acquired, a volume estimate is calculated and presented back to the clinician. The clinician can then exit, restart the tool or save the acquisition to the study roll. The information presented is intended as additional input to standard diagnostic pathways and is only to be used by qualified clinicians.

The Auto 3D Bladder Volume Tool is based on the image segmentation method, U-Net[1], and the volume calculation is computed using the process of integration over binary images.

1. Ronneberger, Olaf, Fischer, Philipp, and Brox, Thomas. "U-net: Convolutional networks for biomedical image segmentation." *International Conference on Medical image computing and computer-assisted intervention*. Springer, Cham, 2015.

Indications for Use:
The Butterfly Auto 3D Bladder Volume Tool is a software application package. It is designed to view, quantify and report results acquired on Butterfly Network ultrasound systems for noninvasive volume measurements of the bladder, to support physician diagnosis. Indicated for use in adult populations.

Summary of Technological Characteristics
The Butterfly Auto 3D Bladder Volume Tool has a substantially equivalent intended use and technological characteristics as the legally marketed predicate device. Quantification and reporting of results of bladder volume is the technological principle for both the subject and predicate devices and are used to aid in diagnosis. The subject and predicate devices are based on the following same technological elements:

- Quantification of bladder volume based on the analysis of on image segmentation data
- Identifying and outlining the bladder
- Auto-contouring of the bladder
- Reporting of bladder volume

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

- The Butterfly Auto 3D Bladder Volume Tool uses the machine learning-based algorithm, U-Net.
    - The predicate has the same intended use and provides machine learning-based algorithms for its bladder volume calculations via patented neural network technology.

A comparison of the proposed Butterfly Auto 3D Bladder Volume Tool to the currently marketed predicate device are provided in the table below:

Comparison Category	**Butterfly Auto 3D Bladder Volume Tool** **(This submission)**	**Predicate Verathon BladderScan Prime PLUS System** **(K172356)**
Comparison Overview		
Intended Use/Indications For Use	The Butterfly Auto 3D Bladder Volume Tool is a software application package. It is designed to view, quantify and report results acquired on Butterfly Network ultrasound systems for noninvasive volume measurements of the bladder, to support physician diagnosis. Indicated for use in adult populations.	The BladderScan Prime System is an ultrasound device intended to be used for measuring the urine volume in the bladder non- invasively.
Contraindications	The Auto 3D Bladder Volume Tool is not intended for fetal or pediatric use or for use on pregnant patients, patients with ascites, or patients with open skin or wounds in the suprapubic region.	The BladderScan Prime System is not intended for fetal use or for use on pregnant patients, patients with ascites, or patients with open skin or wounds in the suprapubic region.
Patient/User Characteristics		
Target Population	Male and Female	Male, Female, and Pediatric
Anatomical Site	Identical to predicate	Bladder

Users	Identical to predicate	Physicians/Medical Professionals
Technological Characteristics and Performance		
Technology	Identical to predicate	Neural network technology
Sterility	Identical to predicate	Non-sterile
Power Source	Identical to predicate	Battery powered
Energy Delivered	Identical to predicate	Ultrasound
Measurement Accuracy	0-100mL = ±7.5mL 100-740 mL = ±7.5%	0-100mL = ±7.5mL 100-999 mL = ±7.5%
Measurement Range	0 to 740 mL	0 to 999 mL
Modes of Operation	B-mode	B-mode
Transducer Type	Electronic Sector Scanning (Phased Array)	Mechanical Sector Probe
Sector Angle	100 degrees	120 degrees
Number of Scan Planes	25	12
Design and Usability Features		
Portable	Identical to predicate	Yes
Display	Identical to predicate	LCD
Scan Button	Identical to predicate	Yes
Touchscreen Operation	Identical to predicate	Yes
Selectable Unit Orientation (Patient Right/Left)	No	Yes
Live Scan Image	Identical to predicate	Yes
Calibration	Identical to predicate	No calibration recommended

Performance Data

Software Verification and Validation Testing

Software verification and validation testing were conducted, and 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, since a failure or latent design flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Performance Testing

Butterfly Network's Auto 3D Bladder Volume Tool software was developed and tested in accordance with company design control processes and safety and performance testing. Verification and validation testing established that the device meets its design requirements, intended use and demonstrates substantial equivalence to the predicate. A non-interventional validation study was conducted, where bladder volume was calculated. The patient dataset was constructed to provide a representative range of volume values, in a patient population with a balanced gender proportion and clinically typical age. Variability testing was also performed to demonstrate that the Auto 3D Bladder Volume Tool performs acceptably with a variety of image clips and frames from the same patient. Test datasets were strictly segregated from algorithm training datasets. The primary endpoint was met. Inter and intra-operator variability was assessed between operators processing the same images. Based on the clinical performance as documented in this study, the device has a safety and effectiveness profile that is equivalent to the predicate.

Summary of Substantial Equivalence:

The Auto 3D Bladder Volume Tool 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 Auto 3D Bladder Volume Tool is safe and effective and therefore, substantially equivalent.