March 27, 2026

Butterfly Network, Inc.
Nathan Sabich
Vice President, Head of Global Quality and Regulatory Affairs
1600 District Avenue
Burlington, Massachusetts 01803

Re: K252148
Trade/Device Name: Butterfly Gestational Age Tool
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 2, 2026
Received: March 3, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

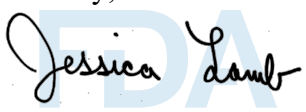
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,



Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252148

Device Name
Butterfly Gestational Age Tool

Indications for Use *(Describe)*
The Butterfly Gestational Age Tool is indicated to provide an output of gestational age (GA) of a singleton intrauterine pregnancy presumed to be between 16-37 weeks gestation. It is for use by qualified and trained healthcare professionals in environments where healthcare is provided. This adjunctive information is not intended to be used for prenatal management and/or delivery planning. The Butterfly Gestational Age Tool is to be used with Butterfly's ultrasound systems (iQ+ or iQ3).

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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K252148
510(k) Summary of Safety and Effectiveness
Butterfly Network, Inc.

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

Date Prepared: March 26, 2026

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

Primary Contact:
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Subject Device - Proprietary/Trade Name: Butterfly Gestational Age Tool

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

Primary Predicate Device Information:

Device Trade Name:	Butterfly iQ3 Ultrasound System
510(k) Number:	K232808
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.

Reference Predicate Device Information:

Device Trade Name:	Voluson Expert Series
510(k) Number:	K231965
Submitter:	GE Healthcare
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

Device Description:

The Butterfly Gestational Age Tool (GA Tool) is a software application that guides trained healthcare professionals through measuring fundal height and obtaining ultrasound cines of a patient's gravid abdomen, using a Butterfly ultrasound probe (iQ+ or iQ3) connected to a tablet. Users launch the tool as a calculation tool within the iQ App's OB scan presets (OB 1/GYN or OB 2/3). Users first measure the fundal height in centimeters, which determines the number of ultrasound videos or "sweeps" needed. These sweeps are short cines captured by moving the probe across the abdomen in specific orientations without relying on the live B-mode. The system presents users with animations for each sweep to communicate the intended path and probe orientation, rather than relying on a live B-mode scan.

The collected sweeps are input into a deep-learning model within the GA Tool. The model then outputs an estimated gestational age. Users can delete the measurement or add additional documentation like patient details or notes. When performing the sweeps, the ultrasound probe makes direct contact with the patient's skin using a coupling medium such as an ultrasound gel.

Once complete, users have the options to delete the measurement or add additional documentation before uploading the results securely to Butterfly's cloud for storage and access by medical professionals. The GA Tool aims to standardize and simplify the process of estimating gestational age using ultrasound technology.

The subject device contains the exact same hardware technology as the previously cleared subject device and no accessories are required to use the GA Tool. The GA Tool is compatible with both the Butterfly iQ3 (primary predicate) and Butterfly iQ/iQ+ Ultrasound Systems. The only change is the new GA Tool, which does not alter the

intended use of the device, nor does it affect the safety and effectiveness of the device relative to the predicate.

Indications for Use:

The Butterfly Gestational Age Tool is indicated to provide an output of gestational age (GA) of a singleton intrauterine pregnancy presumed to be between 16-37 weeks gestation. It is for use by qualified and trained healthcare professionals in environments where healthcare is provided. This adjunctive information is not intended to be used for prenatal management and/or delivery planning. The Butterfly Gestational Age Tool is to be used with Butterfly's ultrasound systems (iQ+ or iQ3).

Summary of Technological Characteristics:

The GA Tool employs the same fundamental scientific technology as its primary predicate device. There are no changes to the overall system design or any of its performance characteristics with the addition of this GA Tool, and the user still interacts with the transducer via the Butterfly iQ application, which runs on a commercial off the shelf (COTS) mobile device and includes a touchscreen display that allows the operator to control the system.

The subject device contains the exact same hardware technology as the predicate device and there are no new features that change the indications for use. Similarly, since there are no changes to the general Butterfly platform, there is no impact to cybersecurity requirements. The GA Tool represents a new Artificial Intelligence (AI) feature that is substantially equivalent to the manual gestational age calculation that has already been cleared in its predicate device. The GA Tool is also substantially equivalent to the *SonoBiometry* feature available on the reference predicate device, an AI-powered tool that automates standard fetal measurements during ultrasound exams.

Summary of Safety and Non-Clinical Performance:

The Butterfly Gestational Age Tool 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 Gestational Age Tool 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 60601-2-5 Ed 3.0 2009-07	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
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	Medical devices - Application of risk management to medical devices

Software Verification and Validation Testing for the Butterfly Gestational Age Tool was also conducted and provided in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Relevant non-clinical verification and validation testing was performed to address the integration of the GA Tool 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.

Butterfly GA Tool Development:

The Butterfly GA tool uses Deep Learning (DL) was developed by University of North Carolina in the Fetal Age Machine Learning Initiative (FAMLI) protocol (UNC IRB #18-1848). In a prospective study, over 100,000 cine loops comprising millions of image frames from thousands of patients from sites within the United States (University of North Carolina) and Zambia were

obtained by POCUS users alongside standard fetal biometry performed by sonographers [1]. The blind ultrasound sweeps (cineloop videos) of the gravid abdomen of the pregnant patients were used to train the Gestational Age DL algorithm to estimate gestational age from the sweeps, the performance of the DL algorithm was assessed compared to biometry and against previously established gestational age [1]. In the main test set, the mean absolute error (MAE) (±SE) was 3.9±0.12 days for the model versus 4.7±0.15 days for biometry (difference, −0.8 days; 95% confidence interval [CI], −1.1 to −0.5; P<0.001) [1]. The results were similar in North Carolina (difference, −0.6 days; 95% CI, −0.9 to −0.2) and Zambia (−1.0 days; 95% CI, −1.5 to −0.5) [1].

[1] Pokaprakarn T, Prieto JC, Price JT, Kasaro MP, Sindano N, Shah HR, Peterson M, Akapelwa MM, Kapilya FM, Sebastião YV, Goodnight W 3rd, Stringer EM, Freeman BL, Montoya LM, Chi BH, Rouse DJ, Cole SR, Vwalika B, Kosorok MR, Stringer JSA. AI Estimation of Gestational Age from Blind Ultrasound Sweeps in Low-Resource Settings. NEJM Evid. 2022 May;1(5):10.1056/evidoa2100058. doi: 10.1056/evidoa2100058. Epub 2022 Mar 28. PMID: 36875289; PMCID: PMC9980216.

Summary of Clinical Performance Tests:

The purpose of the clinical performance evaluation was to evaluate the performance of the Butterfly Gestational Age (GA) Tool functionality with the Butterfly iQ+ and iQ3 system in pregnant subjects with confirmed gestational age ranging from 16 to 37 weeks, in a dataset that is totally independent from that of the Butterfly GA tool development.

One hundred and eleven (111) unique subjects enrolled between March 2025 to February 2026 at 4 USA locations (Site1: Butterfly offices in Burlington-MA, Site2: Thomas Jefferson University in Philadelphia-PA, Site3: Remedy Direct Primary Care in Flagstaff-AZ, Site5: Butterfly offices in NYC-NY). All subjects were scanned with the Butterfly GA tool by 13 trained health care practitioners (7 Physicians and 6 Sonographers), Biometry was performed by the 6 sonographers, both biometry and Butterfly GA Tool measurements were performed at the same subject visit and the Gestational Age from the subject reported Last Menstrual Period (LMP) was recorded.

The Butterfly GA Tool measurements were collected with both the Butterfly iQ+ and the Butterfly iQ3 probe in all 111 subjects, in 1 subject the iQ+ measurement was performed at a different visit/date of the Biometry scan and therefore excluded in the iQ+ data analysis set. The subject's demographics per site/location is presented in Table 1.

Table 1: Subjects demographic information

Site Number	Site 1	Site 2	Site 3	Site 4	Total
Sample Size (n)	58	14	3	36	111
Age (min, max)	(26, 41)	(25, 37)	(27, 30)	(23, 40)	(23, 41)
BMI					
BMI <25 (total)	5	3	0	5	13
BMI 25 to 29.9 (total)	33	6	1	24	64
BMI>30 (total)	20	5	2	7	34
Ethnicity					
Hispanic	6	2	0	15	23
Non-Hispanic	52	12	3	21	88
Race					
Asian	0	1	0	4	5

Black or African American	6	7	0	9	22
Native Hawaiian or Other Pacific Islander	0	0	1	0	1
White	49	4	2	17	72
American Indian or Alaska Native	0	0	0	1	1
Other	3	2	0	5	10
Clinical Conditions					
Diabetes	0	1	0	0	1
Asthma	1	0	1	0	2
Other	0	0	0	4	4
None	57	13	2	32	104

Site 1: Butterfly offices in Burlington-MA
Site 2: Thomas Jefferson University in Philadelphia-PA
Site 3: Remedy Direct Primary Care in Flagstaff-AZ
Site 4: Butterfly offices in NYC-NY

The clinical performance evaluation involved comparing the Butterfly GA Tool error in reference to the Gestational Age calculation from Last Menstrual Period (LMP) to the pre-defined established clinical acceptable error of ultrasound measured gestational age: +/-10 days for Week 16 to 21 6/7, +/- 14 days for Week 22 to 27 6/7, +/- 30 days for Week 28 to 37 6/7. Tables 2 and 3 below present the Bland-Altman bias and Limits of Agreement (LOA) for the Butterfly GA Tool and Biometry against LMP and Butterfly GA Tool against Biometry.

Table 2. Bland Altman bias and LOA estimates for the Butterfly GA Tool with iQ+ and Biometry against LMP, and the Butterfly GA Tool with iQ+ against Biometry.

		Butterfly Gestational Age with iQ+ vs LMP in days		**Biometry Gestational Age vs LMP in days**		**Butterfly Gestational Age with iQ+ vs Biometry Gestational Age in days**	
GA window	**N**	**Bias [95% CI]**	**LOA (Lower [95% CI] / Upper [95% CI])**	**Bias [95% CI]**	**LOA (Lower [95% CI] / Upper [95% CI])**	**Bias [95% CI]**	**LOA (Lower [95% CI] / Upper [95% CI])**
Week 16 to 21 6/7	28	2.64 [0.84 to 4.45]	-6.92 [-10.05 to -3.79] / 12.20 [9.07 to 15.33]	1.96 [0.30 to 3.63]	-6.84 [-9.72 to -3.96] / 10.77 [7.89 to 13.65]	0.68 [-0.69 to 2.05]	-6.24 [-8.60 to -3.87] / 7.59 [5.23 to 9.96]
Week 22 to 27 6/7	37	2.27 [0.55 to 3.99]	-8.20 [-11.14 to -5.26] / 12.74 [9.80 to 15.68]	3.14 [1.50 to 4.77]	-6.84 [-9.68 to -4.00] / 13.11 [10.27 to 15.95]	-0.86 [-2.46 to 0.73]	-10.23 [-12.98 to -7.48] / 8.50 [5.75 to 11.25]
Week 28 to 37 6/7	45	0.51 [-2.27 to 3.29]	-18.16 [-22.98 to -13.34] / 19.18 [14.36 to 24.00]	1.84 [-0.92 to 4.61]	-16.70 [-21.49 to -11.91] / 20.39 [15.60 to 25.17]	-1.33 [-3.04 to 0.37]	-12.47 [-15.41 to -9.53] / 9.80 [6.86 to 12.74]

LOA=Limit of Agreement

Table 3. Bland Altman bias and LOA estimates for the Butterfly GA Tool with iQ3 and Biometry against LMP, and the Butterfly GA Tool with iQ3 against Biometry.

		Butterfly Gestational Age with iQ3 vs LMP in days		**Biometry Gestational Age vs LMP in days**		**Butterfly Gestational Age with iQ3 vs Biometry Gestational Age in days**	
GA window	**N**	**Bias [95% CI]**	**LOA (Lower [95% CI] / Upper [95% CI])**	**Bias [95% CI]**	**LOA (Lower [95% CI] / Upper [95% CI])**	**Bias [95% CI]**	**LOA (Lower [95% CI] / Upper [95% CI])**
Week 16 to 21 6/7	28	-0.50 [-2.42 to 1.42]	-10.68 [-14.02 to -7.35] / 9.68 [6.35 to 13.02]	1.96 [0.30 to 3.63]	-6.84 [-9.72 to -3.96] / 10.77 [7.89 to 13.65]	-2.46 [-3.66 to -1.27]	-8.49 [-10.55 to -6.43] / 3.56 [1.50 to 5.62]
Week 22 to 27 6/7	38	0.61 [-0.93 to 2.14]	-8.84 [-11.49 to -6.19] / 10.05 [7.40 to 12.70]	3.08 [1.48 to 4.68]	-6.78 [-9.55 to -4.01] / 12.94 [10.17 to 15.71]	-2.47 [-4.04 to -0.90]	-11.84 [-14.55 to -9.13] / 6.90 [4.19 to 9.60]
Week 28 to 37 6/7	45	-3.09 [-5.61 to -0.56]	-20.03 [-24.40 to -15.65] / 13.85 [9.48 to 18.22]	1.84 [-0.92 to 4.61]	-16.70 [-21.49 to -11.91] / 20.39 [15.60 to 25.17]	-4.93 [-6.40 to -3.46]	-14.52 [-17.05 to -11.99] / 4.65 [2.12 to 7.18]

LOA=Limit of Agreement

Subgroup analyses looking at the Butterfly GA Tool mean GA error 95% CI for both iQ+ and iQ3 within various relevant covariates (gestational age window, sites/locations, BMI category, healthcare provider type) do not appear to show any appreciable performance difference compared to Biometry.

Summary of Non-Clinical Tests:

Software Verification and Validation Testing as well as Usability Testing was performed to ensure the device performed as intended and is safe and effective.

Summary of Substantial Equivalence:

The Butterfly GA Tool is substantially equivalent to the predicate device (K232808). It is also substantially equivalent to the *SonoBiometry* feature available on the reference predicate, the Voluson Expert Series (K231965). Compared to the primary predicate, every aspect of the subject device remains unchanged - the only change is the addition of the GA Tool.

The following table below provides an overview of the comparison between the subject device and the predicate device.

Model	Butterfly Gestational Age Tool (Subject Device)	Butterfly iQ3 Ultrasound System (K232808, 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/Hardware			
Hand-held portable diagnostic ultrasound system.	✔	✔	Remains Unchanged
Software Features			
Gestational Age Tool	✔	-	New feature - similar feature to manual biometry calculation on the predicate device.

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 Gestational Age Tool does not introduce any new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device (K232808).