July 17, 2026

Natural Cycles Nordic Ab
Megan Callanan
US and Global Regulatory Lead
Sankt Eriksgatan 63 B
Stockholm, 11234
SWEDEN

Re: K253694
Trade/Device Name: Natural Cycles
Regulation Number: 21 CFR 884.5370
Regulation Name: Software Application For Contraception
Regulatory Class: II
Product Code: PYT
Dated: June 16, 2026
Received: June 16, 2026

Dear Megan Callanan:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

The FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), titled “Predetermined Change Control Plan for New

Wearables", version 4.4. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253694

Device Name
Natural Cycles

Indications for Use *(Describe)*
Natural Cycles is a standalone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).

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 – K253694

Applicant:	NaturalCyles Nordic AB Sankt Eriksgatan 63B Stockholm, Sweden 112 34
Applicant Contact:	Name: Megan Callanan Phone: (216)744-4524 Email: Megan.callanan@naturalcycles.com
Date Prepared:	July 16, 2026
Trade Name:	Natural Cycles
Common Name:	Software application for contraception
Regulatory Class:	II
Regulation Name:	Software application for contraception
Regulation Number:	21 CFR 884.5370
Product Code:	PYT (Device, Fertility Diagnostic, Contraceptive, Software Application)
Predicate Device:	K231274 Natural Cycles The predicate device has not been subject to a design-related recall.
Device Description:	Natural Cycles is an over-the-counter and prescription web and mobile-based standalone software application that monitors a woman's menstrual cycle using information entered by the user and informs the user about her past, current and future fertility status. The following information is used by the Natural Cycles software: daily temperature measurements, information about the user's menstruation cycle (i.e., start date, number of days), and optional ovulation or pregnancy test results. A proprietary algorithm evaluates the data and returns the user's fertility status. This 510(k) includes an update to this algorithm, which now includes a model that was developed using machine learning. This model is "locked," meaning it provides the same output each time the same input is applied to it and does not change with use. Natural Cycles is available in five modes: Contraception (NC° Birth Control), Conception (NC° Plan Pregnancy), Pregnancy (NC° Follow Pregnancy), Postpartum (NC° Postpartum), and Perimenopause (NC° Perimenopause). NC° Follow Pregnancy, NC° Postpartum, and NC° Perimenopause are general wellness functions. Users can choose to use Natural Cycles in various modes based on their goals. Inputs to the device include user-inputted daily basal body temperature measured with an oral thermometer with two decimal points or a compatible wearable device (e.g., Oura Ring and Apple Watch). Natural Cycles can be used by women 18 years and older.
Indications for Use:	Natural Cycles is a standalone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).

Comparison of Intended Use and Technological Characteristics with the Predicate Device

A detailed comparison of the intended use and technological features of the subject and predicate device are described in the table below:

Parameter	Subject Device Natural Cycles	Predicate Device Natural Cycles	Comparison
Application Number	K253694	K231274	n/a
Product Code	PYT	PYT	Identical
Regulation Number	21 CFR 884.5370	21 CFR 884.5370	Identical
Indications for Use	A stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).	A stand-alone software application, intended for women 18 years and older, to monitor their fertility. Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).	Identical
Use Environment	App is downloaded to user's smartphone and used in the home environment	App is downloaded to user's smartphone and used in the home environment	Identical
Input Information	● Manual input of two-decimal daily basal body temperature (BBT) measurements or automatic input from a validated third party temperature measuring device. ● Manual input of information about the user's menstruation cycle, i.e. start date, number of days. ● Optional manual input of ovulation or pregnancy test results.	● Manual input of two-decimal daily basal body temperature (BBT) measurements or automatic input from a validated third party temperature measuring device. ● Manual input of information about the user's menstruation cycle, i.e. start date, number of days. ● Optional manual input of ovulation or pregnancy test results.	Identical

Output Information	• NC° Birth Control mode: For each day, whether the woman is fertile (red) or non-fertile (green), with descriptive texts. • NC° Plan Pregnancy mode: Fertility status results are displayed as a scale for fertile days, and green for non-fertile days, together with description texts. All users in NC° Birth Control mode or NC° Plan Pregnancy mode receive the ovulation date for the month and daily statement of fertility status. Historic data is available for all users.	• NC° Birth Control mode: For each day, whether the woman is fertile (red) or non-fertile (green), with descriptive texts. • NC° Plan Pregnancy mode: Fertility status results are displayed as a scale for fertile days, and green for non-fertile days, together with description texts. All users in NC° Birth Control mode or NC° Plan Pregnancy mode receive the ovulation date for the month and daily statement of fertility status. Historic data is available for all users.	Identical
Algorithm	Proprietary Fertility Algorithm (Hybrid Algorithm with three main components: the Statistical Algorithm, the Machine Learning Algorithm (which has a Machine Learning model at its core), and their integration through the Decision Engine)	Proprietary Fertility Algorithm (Statistical Algorithm)	Subject device introduces machine learning component into Proprietary Fertility Algorithm

The subject and predicate devices have identical indications for use statements and have the same intended use – to predict fertile and non-fertile days for use in providing patient-specific recommendations related to contraception. The subject and predicate devices have different technological characteristics (i.e., algorithms). However, these differences do not raise different questions of safety and effectiveness as compared to the predicate device.

Summary of Non-Clinical Performance Testing

Software documentation was provided in accordance with the 2023 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* to support enhanced documentation level software

Cybersecurity information was provided in accordance with the 2025 FDA guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*

Predetermined Change Control Plan

The authorized Predetermined Change Control Plan (PCCP) for Natural Cycles enables Natural Cycles to integrate additional wearable devices as temperature data sources without requiring a new 510(k) submission provided the device meets the acceptance criteria specified in the PCCP.

Under this authorized PCCP, a new wearable device may be qualified as a temperature input source using the same verification and validation protocols used to establish substantial equivalence for previously cleared wearable integrations such as Oura Ring (K202897) and Apple Watch (K231274). There are two options for study design that can be used to

meet the requirements of this PCCP:

1. Protocol v1: active Natural Cycles users are recruited to be part of the study. Participants are given wearable under consideration and are instructed on the study protocol. This protocol was followed for the Oura Ring validation (K202897).
2. Protocol v2: data is collected with permission from active Natural Cycles users who already wear the wearable under consideration. This protocol was followed for the Apple Watch validation (K231274).

After data is collected, the performance KPIs of the wearable under consideration are evaluated. The performance of the new wearable as a temperature input to the Natural Cycles app is characterized through the safety of the product and its contraceptive effectiveness (i.e. the risk of getting pregnant due to a falsely attributed green day) and user satisfaction (i.e. how many unnecessary red days are provided where users are instructed to use protection or abstain from intercourse). If the wearable under consideration meets the PCCP acceptance criteria, the new wearable is determined to perform equivalently to the temperature input sources already cleared for Natural Cycles.

Following successful completion of PCCP validation, a new application version that can receive temperature input data from the new wearable is released through Natural Cycles' Software Lifecycle procedures. Users can download or automatically update their Natural Cycles application through the Apple App store or Google Play store. The Natural Cycles User Manual is updated concurrently to include instructions for the new wearable as a temperature input source option.

Algorithm Description

The updated algorithm consists of three main components: the Statistical Algorithm (which is the algorithm used in previous versions of the Natural Cycles application), the Machine Learning Algorithm, and the Decision Engine. All data are first processed by the Statistical Algorithm. The Machine Learning Algorithm then uses the data logged by the user as well as the outputs of the Statistical Algorithm to estimate the probabilities of ovulation and menstruation. The Decision Engine finally combines the outputs of both the Statistical and Machine Learning Algorithms and acts as a supervisory layer, determining which output should be used for that particular user and cycle. The model used in the Machine Learning Algorithm is "locked," meaning it provides the same output each time the same input is applied to it and does not change with use.

Machine Learning Model Training Description

The Machine Learning model was developed using data collected from over 900,000 Natural Cycles application users who provided informed consent for their anonymized data to be used for research and algorithm development purposes. Natural Cycles is used by women, so only data from women are collected. From this dataset, three subsets were created for training, validation (tuning), and testing purposes. The training dataset comprises 70% of the users, the validation (tuning) dataset includes 10%, and the test dataset contains the remaining 20%. The test dataset is reserved exclusively for evaluating the final model and is not used during the training and validation process. Each user's data is included in only one of these subsets, determined through random selection, thus ensuring that the three datasets are independent. The three datasets were checked to be equally representative of the intended population in terms of age, race and ethnicity.

The ML model was trained using the ovulation identified by the Statistical Algorithm when using both temperatures and LH tests as inputs as well as the user-logged menstruation data as labels.

Summary of Clinical Validation

The clinical validation of the Hybrid Algorithm was conducted analyzing the data included in the test set described in the previous section. The performance of the Hybrid Algorithm was compared with the performance of the predicate device, Statistical Algorithm v3.6.0. A number of pre-defined selection criteria are applied to the dataset. These include filtering out users who never logged any data, and filtering out cycles in which only very few temperatures were logged as well as

conception cycles. Further filtering was applied to ensure that the LH test results logged by the users were reliable. These selection criteria result in a dataset of "complete cycles" and a sub-dataset of "LH-cycles".

Ground truth

In the LH-cycles, the LH-only ovulation (i.e. the ovulation identified only using the LH test results logged by the users) was defined as being 2-days after the LH surge. The LH surge was identified using the pattern of the LH test results. Conversely, for this clinical validation, the two algorithms were run using only temperature and menstruation data as inputs (i.e. the user-logged LH test results are not provided as input to the algorithms). As a result, the outputs of the algorithms were completely independent of the LH data, which can therefore be used as an unbiased ground truth.

Key Performance Indicators

The test set was processed separately with the two algorithms. The performance of the two algorithms were compared through the following key performance indicators (KPIs):

- **Average fraction of green days** : computed as the fraction of green days per cycle averaged over all the cycles. This is computed on all complete cycles.
- **Positive Percentage Agreement (PPA)**: the percentage of the "true fertile days" that were identified as high risk of pregnancy (i.e., red) by the algorithm under scrutiny. The true fertile days were identified using the LH-only ovulation as the reference method and include the ovulation day itself and the five preceding days. This was computed on all LH-cycles.
- **Ovulation detection** : fraction of LH-cycles in which the ovulation was detected with the algorithm under scrutiny. This was computed on all LH-cycles to have an independent indicator that ovulation has indeed occurred.
- **Modified ovulation resolution** (for non-inferiority testing): fraction of LH-cycles in which ovulation was both detected and placed within 2 days of the LH-only ovulation. This definition used an algorithm-independent denominator and permitted paired comparison under the framework described in Section 3.4. This definition was more stringent than the original ovulation resolution defined above.

Of the above KPIs, the average fraction of green days was directly related to the users satisfaction while the PPA was a measurement of the expected safety of the algorithms as it represents the fraction of correctly assigned Red Days (i.e., days when the user is fertile and has a high risk of pregnancy).

Summary of Test Statistics

The performance of the new Hybrid Algorithm was evaluated against the predicate device using a statistical test for non-inferiority applied separately for each KPI. A specific acceptable margin for non-inferiority was prespecified for each KPI, as shown in the table below.

	Non-Inferiority margin	Clinical justification
Average fraction of green days	3.5%	The evaluated algorithm delivers at most 1 fewer green day per cycle compared to the predicate device, on average.
PPA	0.2%	The evaluated algorithm delivers up to 0.012 additional wrongly attributed green days per cycle compared to the predicate device version v3.6.0, on average. Over the course of more than 6 years, a user may be expected to experience up to a single additional wrongly attributed green day.

Ovulation detection	1.0%	Over the course of 7 years, a user may be expected to experience up to a single additional ovulatory cycle in which ovulation is not detected while using the evaluated algorithm instead of the predicate device
Modified ovulation resolution	1.0%	Over the course of 7 years, a user may be expected to experience up to a single additional ovulatory cycle in which ovulation is not both detected and placed within 2 days of the LH ovulation while using the evaluated algorithm instead of the predicate device

Results

A total of 111,446 users passed the selection described above, and a total of 1,031,706 complete cycles are included in the final dataset. The subset of LH cycles includes 102,107 cycles collected by 34,935 users.

The characteristics of the users in the final dataset are shown in the table below.

User characteristics	# of users (111,446)
Regular cycle, %	
yes	88%
no	12%
Country, %	
US	43%
UK	24%
Rest of the World	33%
Temperature measuring device, %	
Oral thermometer	78%
Wearable device	12%
Use of hormonal birth control in the 12 months before becoming a Natural Cycles user, %	
No	48%
Yes	52%
Self reported ethnicity, %	
Not reported	80%
Hispanic or Latina	2%
Not Hispanic or Latina	18%

The characteristics of the complete cycles in the final dataset are shown in the table below

Cycle characteristics	# of complete cycles (1,031,706)
User age at the start of the cycle [years], %	
<20	1%
20-24	13%
25-29	36%
30-34	31%
35-44	18%
⩾45	1%
Cycle length [days], %	
<25	13%
25-29	36%
30-34	31%
35-44	18%
≥44	1%

Key Performance Indicators

The pre-specified KPIs described in the previous section were computed for both the Statistical Algorithm v3.6.0 and the Hybrid Algorithm v1.1.2 separately. Results are shown in the table below. In addition to the KPIs, the table includes their 95% CI estimates as well as the result of the non-inferiority test computed for each KPI.

	Statistical Algorithm v3.6.0	Hybrid Algorithm v1.1.2	Pass the non-inferiority test
Average fraction of green days	48.03% ± 15.31%	48.41% ± 15.37%	Yes
PPA	99.26% (99.21% 99.30%)	99.42% (99.38% 99.46%)	Yes
Ovulation detection	97.59% (97.50% 97.68%)	98.23% (98.14% 98.30%)	Yes
Modified ovulation resolution	88.12% (87.92% 88.31%)	88.85% (88.65% 89.03%)	Yes

Conclusion

The results of the performance testing described demonstrate that Natural Cycles is as safe and effective as the predicate device and supports a determination of substantial equivalence.