March 21, 2025

NaturalCycles Nordic AB
Megan Callanan
US and Global Regulatory Lead
Sankt Eriksgatan 63 B
Stockholm, 112 34
SWEDEN

Re: K250561
Trade/Device Name: Natural Cycles
Regulation Number: 21 CFR 884.5370
Regulation Name: Software Application for Contraception
Regulatory Class: II
Product Code: PYT
Dated: February 25, 2025
Received: February 25, 2025

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: 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.

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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250561 ?
Please provide the device trade name(s).	?
Natural Cycles	
Please provide your Indications for Use below.	?
Natural Cycles is 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).	
Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C) ?

510(k) Summary

K250561 - Natural Cycles

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:	March 20, 2025
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. Users can choose to use Natural Cycles in various modes based on their goals. Natural Cycles is available in three modes: Contraception (NC° Birth Control), Conception (NC° Plan Pregnancy), and Pregnancy (NC° Follow Pregnancy). For NC° Birth Control mode, the device provides predictions of "not fertile," shown as green days, and "use protection," shown as red days, that allow the user to determine the days on which her risk of conception is highest, and then make choices about either abstaining from sex or using a barrier method of

	contraception to prevent pregnancy. 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. Women who have been on hormonal birth control within 60 days prior to using Natural Cycles have a higher risk of becoming pregnant when compared to women who have not been on hormonal birth control within the 12 months prior to using the device. This device may not be right for women who have a medical condition where pregnancy would be associated with a significant risk to the mother or the fetus
Indications for Use:	Natural Cycles is 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).

Summary of Technical Characteristics:

The technology of the Natural Cycles Application is identical to the predicate device.

Parameter	**Predicate Device Natural Cycles K231274**	**Subject Device Natural Cycles K250561**	**Comparison**
Indications for Use Statement	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).	Same
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	Same
Type of Use	Over-The-Counter Use	Prescription Use and Over-The-Counter Use	Different – The change from over-the-counter to both over-the-counter and prescription use does not raise different questions of safety and effectiveness.
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.	Same

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. ● NC° Follow Pregnancy mode: Provides educational information about the progress of the pregnancy. 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. ● NC° Follow Pregnancy mode: Provides educational information about the progress of the pregnancy. 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.	Same

Discussion of Differences

As outlined in the table above, the subject and predicate device have identical indications for use statements. The devices differ in the inclusion of prescription use as well as over-the-counter use for the subject device. No changes have been made to the device technology, meaning there are no differences between Natural Cycles cleared under K231274 and the proposed device. The change to prescription and over-the-counter use does not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

There have been no changes to the technology of the device, and no new risks or increased likelihood or magnitude of identified risks have been introduced due to the change from over-the-counter to prescription and over-the-counter use. Therefore, no performance data is needed to validate this change.

Conclusion

The information outlined above is sufficient to demonstrate that the subject device (Natural Cycles) is as safe and effective as the predicate device and supports a determination of substantial equivalence.