



July 11, 2024

NaturalCycles Nordic AB  
Megan Callanan  
Senior Regulatory and Compliance Specialist  
St Eriksgatan 63B  
Stockholm, 112 34  
SWEDEN

Re: K241006  
Trade/Device Name: Natural Cycles  
Regulation Number: 21 CFR 884.5370  
Regulation Name: Software Application for Contraception  
Regulatory Class: II  
Product Code: PYT  
Dated: April 19, 2024  
Received: April 19, 2024

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.

The FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), "Predetermined Change Control Plan for New Wearables", version number 4.2. 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 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.

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](mailto: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

510(k) Number (if known)

K241006

Device Name

Natural Cycles

Indications for Use (Describe)

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).

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

### K241006 – Natural Cycles

Submitter:	NaturalCycles Nordic AB St Eriksgatan 63b 112 34 Stockholm, Sweden
Submitter Contact:	Name: Megan Callanan Phone: (216)744-4524 Email: <a href="mailto:Megan.callanan@naturalcycles.com">Megan.callanan@naturalcycles.com</a>
Date Prepared:	June 25, 2024
<b>Device Name and Classification Information</b>	
Trade Name:	Natural Cycles
Common Name:	Software application for contraception
Regulation Name:	Software application for contraception
Regulation Number:	21 CFR 884.5370
Regulatory Class:	II
Product Code:	PYT (Device, fertility diagnostic, contraceptive, software application)
<b>Predicate Device</b>	
	K231274 Natural Cycles The predicate device has not been subject to a design-related recall.
<b>Device Description</b>	
	<p>Natural Cycles is an over-the-counter 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:</p> <ul style="list-style-type: none"> <li>● daily temperature measurements</li> <li>● information about the user’s menstruation cycle (i.e., start date, number of days)</li> <li>● optional ovulation or pregnancy test results.</li> </ul> <p>A proprietary algorithm evaluates the data and returns the user’s fertility</p>

	<p>status.</p> <p>Natural Cycles is available in three modes: Contraception (NC° Birth Control), Conception (NC° Plan Pregnancy), and Pregnancy (NC° Follow Pregnancy).</p> <p>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.</p> <p>In addition to measuring daily basal body temperature with an oral thermometer with two decimal points, previous submissions cleared the Oura Ring and Apple Watch for automatic temperature input to the Natural Cycles algorithm.</p> <p>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.</p> <p>The subject of this submission is the proposed inclusion of a Predetermined Change Control Plan (PCCP) that enables use of a broader range of temperature measuring devices for future wearable integrations with the Natural Cycles application. There are no changes to the Natural Cycles application from the application cleared in K231274.</p>
<b>Indications for Use</b>	
	<p>Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility.</p> <p>Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).</p>

**Comparison with 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 K241006	Predicate Device Natural Cycles K231274	Comparison
Indications for Use statement	<p>Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility.</p> <p>Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).</p>	<p>Natural Cycles is a stand-alone software application, intended for women 18 years and older, to monitor their fertility.</p> <p>Natural Cycles can be used for preventing a pregnancy (contraception) or planning a pregnancy (conception).</p>	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
Input Information	<ul style="list-style-type: none"> <li>• Manual input of two-decimal daily basal body temperature (BBT) measurements or automatic input from a validated third party temperature measuring device.</li> <li>• Manual input of information about the user's menstruation cycle, i.e., start date, number of days.</li> <li>• Optional manual input of ovulation or pregnancy test results.</li> </ul>	<ul style="list-style-type: none"> <li>• Manual input of two-decimal daily basal body temperature (BBT) measurements or automatic input from a validated third party temperature measuring device.</li> <li>• Manual input of information about the user's menstruation cycle, i.e., start date, number of days.</li> <li>• Optional manual input of ovulation or pregnancy test results.</li> </ul>	Same
Output Information	<ul style="list-style-type: none"> <li>• NC Birth Control mode: For each</li> </ul>	<ul style="list-style-type: none"> <li>• NC Birth Control mode: For each</li> </ul>	Same

		<p>day, whether the woman is fertile (red), or non-fertile (green), with descriptive texts.</p> <ul style="list-style-type: none"> <li>• NC Plan Pregnancy mode: Fertility status results are displayed as a scale for fertile days, and green for non-fertile days, together with descriptive texts.</li> <li>• NC Follow Pregnancy mode: Provides educational information about the progress of the pregnancy.</li> <li>• 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.</li> </ul>	<p>day, whether the woman is fertile (red), or non-fertile (green), with descriptive texts.</p> <ul style="list-style-type: none"> <li>• NC Plan Pregnancy mode: Fertility status results are displayed as a scale for fertile days, and green for non-fertile days, together with descriptive texts.</li> <li>• NC Follow Pregnancy mode: Provides educational information about the progress of the pregnancy.</li> <li>• 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.</li> </ul>	
<p>As outlined in the table above, the subject and predicate device have identical indications for use statements and have the same intended use. The subject and predicate device have identical technological characteristics. In addition, the subject device includes a PCCP to validate future wearables to be used with the Natural Cycles application. The inclusion of the PCCP in the subject devices does not raise different questions of safety and effectiveness.</p>				

<p>Summary of Non-Clinical and/or Clinical Performance Testing</p>	<p>A PCCP was submitted to obtain authorization from FDA to add more wearables providing temperature as an input to the Natural Cycles fertility algorithm in the future without requiring additional 510(k)s.</p> <p>Key Performance Indicators (KPIs):</p> <ul style="list-style-type: none"> <li>● <b>Positive Percent Agreement (PPA)</b> to assess product safety and contraceptive effectiveness, i.e., how often the user is exposed to a pregnancy risk because of a wrongly flagged green day in the fertile window.</li> <li>● <b>Fraction of green days</b> assigned by the fertility algorithm over the total number of days for a given cycle, then averaged over all cycles.</li> <li>● <b>Day to day variability (std)</b> – the standard deviation of the daily temperature values.</li> <li>● <b>Ratio</b> between the temperature phase separation and the standard deviation, i.e., the temperature difference between the pre-ovulatory and post-ovulatory phases of the menstrual cycles.</li> <li>● <b>Detected ovulations</b> – the fraction of cycles with positive LH where ovulation is detected by the Natural Cycles algorithm using the temperatures from the device under consideration as input.</li> <li>● <b>Ovulation resolution</b> – fraction of cycles with positive LH and ovulation detected, where ovulation is detected within two days from the LH-only ovulation day.</li> </ul> <p>Specifications:</p> <table border="1" data-bbox="451 1291 1494 1627"> <thead> <tr> <th>KPI</th> <th>Specification</th> </tr> </thead> <tbody> <tr> <td>Std</td> <td>CI upper bound <math>\leq 0.234</math></td> </tr> <tr> <td>Ratio</td> <td>CI lower bound <math>\geq 2.04</math></td> </tr> <tr> <td>Ovulation detection</td> <td>CI lower bound <math>\geq 85.5\%</math></td> </tr> <tr> <td>Ovulation resolution</td> <td>CI lower bound <math>\geq 76.1\%</math></td> </tr> <tr> <td>PPA</td> <td>CI lower bound <math>\geq 96.5\%</math></td> </tr> <tr> <td>Fraction of green days</td> <td>No more than 2 additional red days per cycle compared to the oral thermometer</td> </tr> </tbody> </table>	KPI	Specification	Std	CI upper bound $\leq 0.234$	Ratio	CI lower bound $\geq 2.04$	Ovulation detection	CI lower bound $\geq 85.5\%$	Ovulation resolution	CI lower bound $\geq 76.1\%$	PPA	CI lower bound $\geq 96.5\%$	Fraction of green days	No more than 2 additional red days per cycle compared to the oral thermometer
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<p><b>Conclusion</b></p>															

Traditional 510(k)  
K241006 - Natural Cycles

	The information outlined above demonstrates that Natural Cycles is as safe and effective as the predicate device and supports a determination of substantial equivalence.
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