June 24, 2021

Natural Cycles Nordic AB
% Sheila Hemeon-Heyer, JD, RAC
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Re: K202897
Trade/Device Name: Natural Cycles
Regulation Number: 21 CFR§ 884.5370
Regulation Name: Software Application for Contraception
Regulatory Class: II
Product Code: PYT
Dated: May 17, 2021
Received: May 17, 2021

Dear Sheila Hemeon-Heyer:

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,

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

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)*
K202897

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

K202897 - Natural Cycles

A. Submitter:

NaturalCycles Nordic AB
St Eriksgatan 63B
112 34 Stockholm, Sweden
Contact: Raoul Scherwitzl, PhD, CEO and Co-Founder

Phone: +46 707174866
E-mail: Raoul.scherwitzl@naturalcycles.com

B. Correspondent:

Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, MA 01002

Contact: Sheila Hemeon-Heyer
E-mail: Sheila@heyer-regulatory.com

C. Date Prepared: June 23, 2021

D. Device Name and Classification Information:

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)

E. Predicate Device(s): DEN170052 Natural Cycles

The predicate device has not been subject to a design-related recall.

F. Device Description:

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:

- daily body temperature measurements
- information about the user's menstruation cycle (i.e., start date, number of days)
- optional ovulation or pregnancy test results

A proprietary algorithm evaluates the data and returns the user's fertility status.

Natural Cycles is available in three modes: Contraception, Conception, and Pregnancy. For Contraception 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.

In addition to measuring daily basal body temperature with an oral thermometer with two decimal points, the device allows automatic temperature input from the Oura ring, a wearable temperature monitor.

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.

G. Indications for Use Statement

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).

H. 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 K202897	Predicate Device Natural Cycles DEN 170052	Comparison
Indications for Use Statement	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).	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).	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 the Oura ring. ● 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. ● 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.	Expanded option for a new source of daily basal body temperature information..

Output Information	● Prevent mode: For each day, whether the woman is fertile (red) or non-fertile (green), with descriptive texts. ● Plan mode: Fertility status results are displayed as a scale for fertile days, and green for non-fertile days, together with description texts. ● Pregnancy mode: Provides educational information about the progress of the pregnancy. ● All uses in Prevent mode or Plan mode receive the ovulation date for the month and daily statement of fertility status. Historic data is available for all users.	● Prevent mode: For each day, whether the woman is fertile (red) or non-fertile (green), with descriptive texts. ● Plan mode: Fertility status results are displayed as a scale for fertile days, and green for non-fertile days, together with description texts. ● Pregnancy mode: Provides educational information about the progress of the pregnancy. All uses in Prevent mode or Plan mode receive the ovulation date for the month and daily statement of fertility status. Historic data is available for all users.	Identical

The subject and predicate device 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 device have different technological characteristics (i.e., temperature data input sources). This difference does not raise different questions of safety and effectiveness as compared to the predicate device.

I. Summary of Non-Clinical Performance Testing

- Software documentation provided in accordance with the 2005 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* to support device software with a major level of concern.

- Cybersecurity information provided in accordance with the 2014 FDA guidance document *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

- Human factors testing in DEN170052 was used to support that device users could safely use the device.

J. Summary of Clinical Performance Testing

The purpose of this 510(k) is to add the option for the user to obtain the daily basal body temperature information used by the Natural Cycles fertility algorithm from the Oura ring, a wearable temperature monitor. There have been no changes to how the Natural Cycles algorithm determines the daily fertility status.

A clinical study was conducted to compare the daily temperatures generated by a wearable

temperature monitor, the Oura ring, to a two decimal place oral thermometer for use by the NaturalCycles algorithm. The study included 40 women who were experienced users of both Natural Cycles and entering their daily temperature using an oral thermometer but did not have experience using the Oura ring with Natural Cycles. The mean age of the study participants was 31.3 ± 4.9 years, and the mean menstrual cycle length for complete cycles during the study was 28.6 ± 4.4 days. The majority (38) of the women were located in Sweden, with one each in the US and Switzerland.

The women wore the Oura ring nightly, with the user's temperature information automatically synced to the Oura Cloud each morning, and also recorded their temperature each morning as taken using a two-decimal place oral thermometer. Data were collected over a total of 223 menstrual cycles, 155 of which were considered complete cycles per the study definition. The participants were also asked to record the results of luteinizing hormone (LH) tests each cycle. At least one positive LH test was submitted in 87 of the complete study cycles.

The results of the clinical study demonstrated that when temperature was inputted from either the Oura ring or the two-decimal place oral thermometer, the Natural Cycles algorithm was able to identify that ovulation had occurred, which was confirmed in the study by comparison to the 87 positive LH test results. Compared to the two-decimal place oral thermometer, the Natural Cycles algorithm provides additional 1.6 green days (not fertile) in the luteal phase of the menstrual cycle when the input temperature was from the Oura ring, without increasing the risk of unintended pregnancy.

K. Conclusion

A comparison of intended use and technological characteristics combined with performance data demonstrates that Natural Cycles is as safe and effective as the predicate device and supports a determination of substantial equivalence. Natural Cycles meets the special controls outlined in 21 CFR 884.5370, Software application for contraception.