August 10, 2018

Natural Cycles Nordic AB
% Sheila Hemeon-Heyer
President and Founder
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: DEN170052
Trade/Device Name: Natural Cycles
Regulation Number: 21 CFR 884.5370
Regulation Name: Software application for contraception
Regulatory Class: Class II
Product Code: PYT
Dated: September 20, 2017
Received: September 20, 2017

Dear Sheila Hemeon-Heyer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Natural Cycles, an over-the-counter device under 21 CFR Part 801 Subpart C with the following 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).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Natural Cycles, and substantially equivalent devices of this generic type, into Class II under the generic name software application for contraception.

FDA identifies this generic type of device as:

> **Software application for contraception**. A software application for contraception is a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (e.g., temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on August 28, 2017 automatically classifying the Natural Cycles in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II.

On September 20, 2017, FDA received your De Novo requesting classification of the Natural Cycles device. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Natural Cycles into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Natural Cycles device can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Unintended pregnancy	Software verification, validation, and hazard analysis; Clinical performance testing; Human factors and usability testing; and Labeling

In combination with the general controls of the FD&C Act, the software application for contraception is subject to the following special controls:

1. Clinical performance testing must demonstrate the contraceptive effectiveness of the software in the intended use population.

2. Human factors performance evaluation must be provided to demonstrate that the intended users can self-identify that they are in the intended use population and can correctly use the application, based solely on reading the directions for use for contraception.

3. Software verification, validation, and hazard analysis must be performed. Documentation must include the following:

    a. A cybersecurity vulnerability and management process to assure software functionality; and

b. A description of the technical parameters of the software, including the algorithm used to determine fertility status and alerts for user inputs outside of expected ranges.

4. Labeling must include:

a. The following warnings and precautions:

i. A statement that no contraceptive method is 100% effective.

ii. A statement that another form of contraception (or abstinence) must be used on days specified by the application.

iii. Statements of any factors that may affect the accuracy of the contraceptive information.

iv. A warning that the application cannot protect against sexually transmitted infections.

b. Hardware platform and operating system requirements.

c. Instructions identifying and explaining how to use the software application, including required user inputs and how to interpret the application outputs.

d. A summary of the clinical validation study and results, including effectiveness of the application as a stand-alone contraceptive and how this effectiveness compares to other forms of legally marketed contraceptives.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the software application for contraception they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Paige Brown at 301-796-6417.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health