Natural Cycles

FDA Factsheet

1. What is the FDA and what does it do?

The FDA (The Food and Drug Administration) is a federal agency in the U.S. that is responsible for protecting and promoting public health. The FDA regulates a wide range of products, including foods, human drugs and medical devices.[1]

2. The Natural Cycles app is cleared as a Class II medical device by the FDA. What does this mean?

The FDA has a risk-based classification system where medical devices are assigned to one of the three regulatory classes: Class I, II, or III.[1] The Natural Cycles app has been classified as a Class II device.[2]

Being FDA cleared means that the Natural Cycles is a legitimate medical device for use as a method of birth control in the U.S., under the regulation of the FDA.[2]

3. Which regulatory pathway did Natural Cycles go through?

For new medical devices in Class II, there are two regulatory pathways to secure clearance — the 510(k) and De Novo pathways.

510(k)

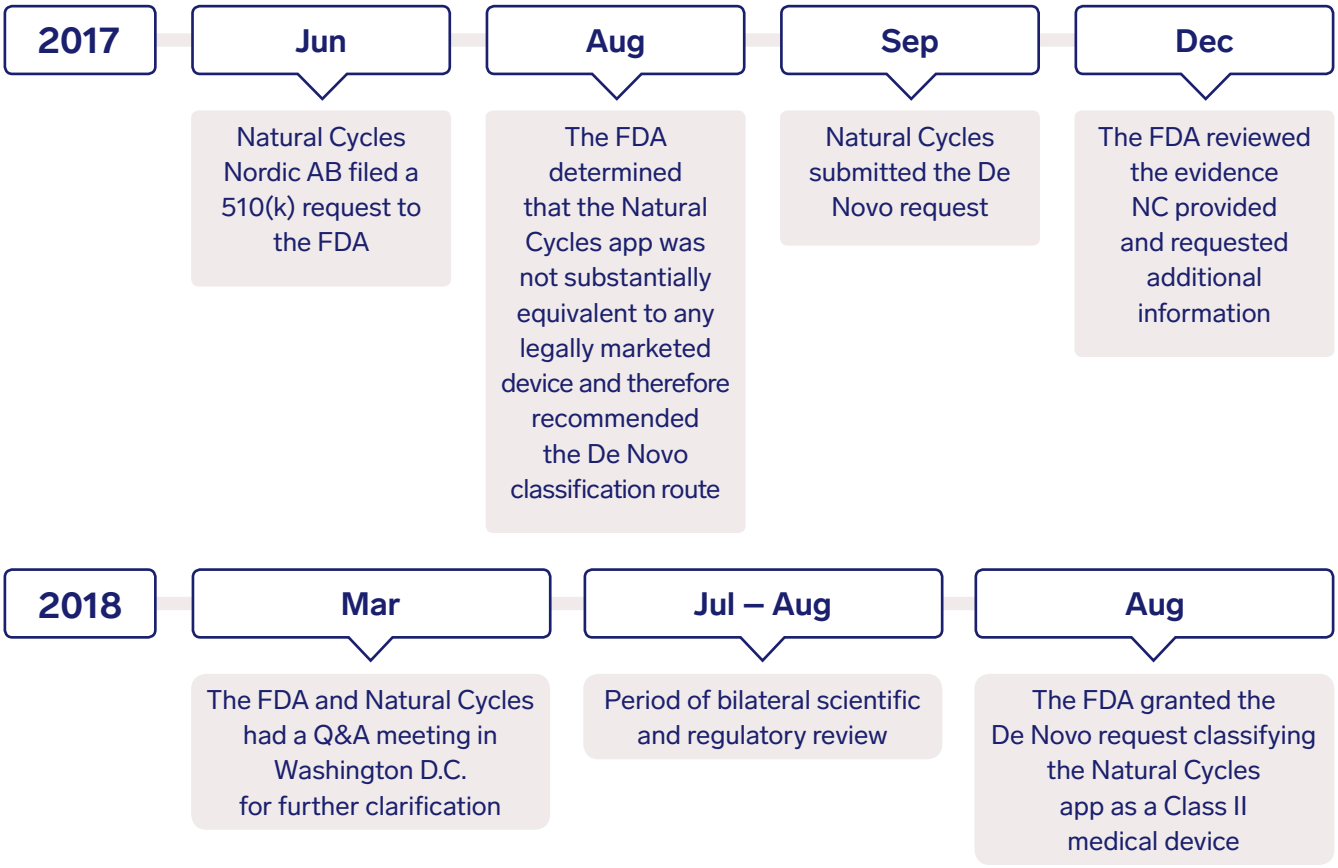
510(k) is the most common regulatory pathway, where manufacturers provide data to demonstrate that their product is substantially equivalent to an existing legally marketed device (*predicate device*).

De Novo pathway

De Novo pathway, on the other hand, is for new, novel medical devices for which there is no valid predicate device — i.e. there is nothing comparable in existence.

Initially, Natural Cycles filed a 510(k) application, but the filing was escalated to the de novo pathway since there was no legally marketed device similar to the Natural Cycles app. In August 2018, Natural Cycles became the first app of its kind to be cleared by the FDA as a method of birth control, setting the framework and guidance for future clearances of a similar nature.[3]

Regulatory Journey



4. What clinical data did the FDA examine?

The FDA evaluated results from three clinical studies,[4,5,6] which included more than 22,000 women; following this review, it requested an additional analysis to isolate data from women who were using the app with the most recent algorithm version (version 3).[2] This prospective analysis involved 15,570 women, who used the app for an average of eight months.[2]

Based on its analysis of these data, the FDA cleared Natural Cycles as a Class II medical device for use as a method of birth control.[3]

5. What other data did the FDA examine?

Beyond clinical information, Natural Cycles provided detailed software-related documentation.

The documentation described:

Design of the software
Implementation of the design
Software testing process
Identification and management of hazards and risks
Traceability steps
Handling and protection of personal data in accordance with regulations and standards

According to the FDA, the documentation provided sufficient evidence of safe and effective software performance.[2]

6. What ongoing monitoring measures are in place?

As a medical device manufacturer, Natural Cycles is subject to assessments and inspections from the FDA.

The FDA also closely monitors adverse events through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. The program allows manufacturers, health care professionals and consumers to report serious problems related to the use of drugs and medical devices.[1]

7. To what extent does the FDA regulate mobile health, lifestyle and medical apps?

The FDA recognizes that digital health technologies can empower consumers to make better-informed decisions about their own health as well as providing a host of potential benefits for the prevention and management of chronic conditions.[7]

Its aim is to encourage innovation while ensuring the safety and efficacy of digital health products, including mobile medical apps – focusing not on everyday health and lifestyle devices, but on the more sophisticated technologies that can have a greater impact on public health.

In its Digital Health Innovation Action Plan,[8] the FDA notes that it is adapting its digital health regulatory pathway to support and keep pace with the speed of innovation in this space.

References

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