January 15, 2021

Ava AG
Blathnaid Feldman
Director Quality and Regulatory Affairs
Gustrasse 73
Zürich 8055
Switzerland

Re: K200163
Trade/Device Name: Ava Fertility Tracker
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LHD
Dated: December 4, 2020
Received: December 7, 2020

Dear Blathnaid Feldman:

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,

For
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

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)*
K200163

Device Name
Ava Fertility Tracker

Indications for Use *(Describe)*
The Ava Fertility Tracker is intended to measure and display physiological parameters (body temperature, resting pulse rate, heart rate variability, and breathing rate) as an aid in ovulation prediction to facilitate conception (not to be used for contraception).

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
K200163
Ava Fertility Tracker

Date Prepared	January 14, 2020
Applicant	Ava AG Gutstrasse 73 CH-8055 Zurich Switzerland
Contact Person	Agata Sroka, Senior Regulatory Affairs Manager Agata.Sroka@avawomen.com
US Contact Person	Stephen La Barbera, VP Marketing & Sales Ava Science Inc. 77 Geary Street, 5th Floor San Francisco, CA 94108 USA Stephen.LaBarbera@avawomen.com
Proprietary Name	Ava Fertility Tracker
Common Name	Proceptive Fertility Tracker
Device Classification	Unclassified
Product Code	LHD (Device, Fertility Diagnostic, Proceptive)
Predicate Device	Lady-Comp® USA (K050094) The predicate device has not been subject to a design-related recall.
Device Description	The Ava Fertility Tracker aids women in ovulation prediction and to facilitate conception. The Ava Fertility Tracker is a non-invasive device made up of the following components: • The Ava bracelet incorporating hardware with electronics and embedded software • A mobile application running on smartphones (iOS and Android) • A backend server software, including algorithms running on remote servers The Ava bracelet is worn by women at night and tracks the following physiological parameters with built-in sensors: • Temperature sensor – provides information on skin temperature • Photoplethysmography (PPG) sensor – measures the interbeat interval (IBI) providing information on pulse rate (HR), heart rate variability (HRV), breathing rate (BR) and perfusion. Only HR, HRV, and BR are used by the algorithms for prediction of the fertile window. Perfusion information is used to assess the quality of the PPG sensor data.

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- Accelerometer – provides information on movement and sleep duration and phases

The user synchronizes the bracelet to the mobile app each morning. The mobile app receives the raw datasets via Bluetooth Low Energy (BLE) and transfers this data to the backend server. The algorithm is run on the physiological parameters collected and the prediction of ovulation and the fertile window is determined. This information is transferred and displayed in the mobile app. The mobile app will also display a single mean value for HR, temperature, HRV ratio, BR, and sleep duration from the prior night.

The mobile application has three modes:

- Trying to Conceive Mode – The application shows the user the predicted day of ovulation plus five predicted fertile days leading up to the predicted day of ovulation. Users receive the prior night summary of measured parameters displayed in graphs. Users can track additional information on their cycle, such as sexual intercourse or cervical fluid (this information does not feed into the algorithm).
- Cycle Tracking Mode– For users not wanting to conceive but wanting to track their cycle. These users receive the same information provided to Trying to Conceive Mode users.
- Pregnancy Mode - Users receive the prior night summary of measured parameters displayed on graphs. They can also track additional information as relates to their pregnancy, such as their weight or their daily water intake. For each week of their pregnancy, a different piece of informational content gets displayed in the application, such as typical height and weight of a baby at this stage of their pregnancy.

Indications for Use

The Ava Fertility Tracker is intended to measure and display physiological parameters (body temperature, resting pulse rate, heart rate variability, and breathing rate) as an aid in ovulation prediction to facilitate conception (not to be used for contraception).

Comparison of Subject and Predicate Device Intended Use and Technological Characteristics

The table below includes a comparison of intended use and technological characteristics of the subject and predicate devices:

Parameter	Subject Device K200163 Ava Fertility Tracker	Predicate Device K050094 Lady-Comp Fertility Monitor	Comparison
Indications for Use	The Ava Fertility Tracker is intended to measure and display physiological parameters (body temperature, resting pulse rate, heart rate variability, and	Lady-Comp USA is intended for measuring and recording basal body temperature (BBT) as an aid in ovulation prediction to facilitate	Although there are differences in the indications for use statements, the intended uses for both devices are the same (i.e., an aid in ovulation prediction and to facilitate conception).

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	breathing rate) as an aid in ovulation prediction to facilitate conception (not to be used for contraception).	conception (not to be used for contraception).	
General Design	Watch-style sensor bracelet, phone app, backend server	Oral temperature sensor attached to reader by a cable	**Different:** The predicate device has a temperature sensor connected to a reader loaded with the prediction algorithm that provides information on the fertility status of the user. The subject device includes a wrist-worn sensor that wirelessly transmits data to an app that connects to a server where the fertility algorithms analyze the information collected and transfer the prediction to the app for display to the user. These differences do not raise different questions of safety and effectiveness (S&E).
Sensors	Temperature PPG Sensor Accelerometer	Temperature	**Different:** The subject device includes additional sensors to collect additional information that is used in by the fertility prediction algorithm. The addition of different sensors does not raise different questions of S&E.
Parameters Measured	Skin temperature Resting pulse rate Breathing rate Heart rate variability (HRV) Sleep duration/ sleep phases Movement Perfusion	Temperature	**Different:** The subject device collects additional physiological information beyond that of the predicate for use by the fertility algorithm and for data integrity purposes. The collection of these additional parameters does not raise different questions of S&E
Number of Measurements Taken	Periodically each night while sleeping	Single measurement upon waking	**Different:** The subject device collects data throughout the night, while the predicate is only used once per day upon waking. Collecting data over a longer period does not raise different questions of S&E.
Location of Temperature Measurement	Wrist – skin	Oral	**Different:** The subject device incorporates a wrist-worn sensor, while

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			the predicate uses an oral temperature probe. Use of a wrist-worn sensor does not raise different questions of S&E.
Temperature Sensor Accuracy/Precision	±0.8°C/ ±0.2°C	± 0.05ºC/unknown	**Different:** The accuracy of the temperature sensor is higher for the predicate device than the subject device. This difference does not raise different questions of S&E.
User Inputs	User can input: • Period/flow information • Cervical fluid consistency • Sexual intercourse • Pregnancy test results • Mood • 10 user defined functions	Not reported in predicate 510(k) Summary	**Different:** The specific user inputs for the predicate device are not known. However, the ability to input additional information for tracking does not raise different questions of S&E.
User Interface	• Smartphone app showing graphical display of the fertility status (5-6 days) • Fertile Days • Ovulation day • Additional parameters measured (e.g., HRV) for general wellness information • User inputs	Per predicate 510(k) Summary the user interacts with the display on the physical device displaying the measured temperature.	**Different:** The subject device provides information via a smartphone app, while the predicate device displays information on the screen of the device. Differences in user interfaces do not raise different questions of S&E.
Power Source	Rechargeable battery	Not reported in predicate 510(k) Summary	**Different:** Information on the specific power sources for the predicate device are not known. However, differences in in power sources do not raise different questions of S&E.
Data Transmission Method from Sensor to Reader	Bluetooth Wireless (wrist sensor to app on phone) Wi-Fi (phone to backend server)	None	**Different:** The predicate device transfers information from the probe to the reader using an attached cable. The subject device uses wireless technology to transfer information between device components. This difference does not raise different questions of S&E

As shown in the table above, there are differences in the subject and predicate device indications for use statements. However, the intended uses of both devices are the same as they are both for aiding in ovulation prediction to facilitate conception and not to be used for contraception.

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The subject and predicate devices have different technological characteristics as shown in the table above. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Data

Biocompatibility Testing

Biocompatibility testing for the Ava Fertility Tracker device was conducted in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* as follows:

- Cytotoxicity: ISO 10993-5:2009
- Skin Irritation: ISO 10993-10:2010
- Sensitization (Guinea Pig Maximization Model): ISO 10993-10:2010

Testing confirmed that the subject device materials are biocompatible.

Software and Cybersecurity

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 minor 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*.

Electrical Safety and EMC Testing

Electrical safety of the Ava Fertility Tracker was tested in accordance with:

- AAMI/ANSI ES 60601-1:2005/A2:2010 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)
- IEC 60601-1-11:2015 (Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment)

Photobiological safety was conducted in accordance with IEC 62471:2006 (Photobiological safety of lamps and lamp systems)

Battery testing conducted in accordance with IEC 62133-1:2012 (Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications)

Electromagnetic compatibility of the Ava Fertility Tracker was tested in accordance with IEC 60601-1-2:2014 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests)

Wireless Technology

Wireless technology information provided in accordance with the 2013 FDA guidance document *Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff*.

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Performance Testing - Bench

Bench testing shown in the table below was conducted to demonstrate that the Ava Fertility Tracker device meets its predetermined performance specifications.

Test name	Summary	Specification	Pass / Fail
Transportation test	Drop test of Device Under Test (D.U.T.) in transportation box	D.U.T. functional and no visual damage	Pass
Connector mating test	Check expected mating cycles of charging connector within component specification	>1460 cycles	Pass
Battery Test 1	Lifetime test after 730 charging / discharging cycles	Battery retains >50% capacity	Pass
Battery Test 2	Sufficient battery capacity at end of life with aged D.U.T.	Valid physiological data transferred to app after one night of data collection	Pass
Cyclic strap elongation	Cyclic elongation of strap following 730 cycles of elongation and relaxation by 15%	Maximum 10% of straps break completely	Pass
Drop Test	Drop D.U.T. from 1.5 m onto hard surface (10 drops)	D.U.T. functional and no visual damage	Pass
Shock test	Acceleration of 15g is applied to D.U.T. (54 shocks)	D.U.T. functional and no visual damage	Pass
Vibration test	Broad band random vibration excitation is applied to D.U.T. for 4.5h	D.U.T. functional and no visual damage	Pass
Load Test	Mechanical load of 250N is applied to D.U.T. for 1 hour	D.U.T. functional and no visual damage	Pass
Perfume / insect repellent test	Perfume and insect repellent applied to D.U.T.	D.U.T. functional and no visual damage	Partial pass – Labeling to avoid exposure

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	housing (30-day exposure)		to ethanol-containing products
Cosmetic cream test	Cosmetic cream applied to D.U.T. housing (30-day exposure)	D.U.T. functional and no visual damage	Pass
Sweat test	Artificial sweat applied to D.U.T. housing (30-day exposure)	D.U.T. functional and no visual damage	Pass
Temperature sensor validation	Accelerated aging test to assess temperature sensor function over time	The temperature sensor chip stays within specification: Precision: ±0.2°C Accuracy: ±0.8°C	Pass
Accelerometer sensor validation	Accelerated aging test to assess accelerometer function over time	Accuracy <± 0.02 g Precision <± 0.001g	Partial Pass – Precision met at all timepoints, while accuracy passed in aged devices. Justification provided in support of precision as the more important factor as the device only uses relative acceleration changes that are used in the sleep state computation.
PPG sensor Validation	Assessed the ability of the device to measure IBI, HR, BR, and HRV	PPG sensor signal ±3% error for IBI and HR, and <2.5% signal error for BR and HRV	Pass

Summary of Clinical Data

Performance Testing - Clinical

A single center, prospective clinical study was conducted to support the subject device. The study enrolled 66 women between the ages of 18 and 45 years of age that were not planning to become pregnant in the following three to six months. Also, the women enrolled in the study were not on hormonal birth control, breastfeeding or taking medications that could affect the menstrual cycle. They also did not have any health issues, frequently travel between time

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zones or have a sleeping disorder. The final analysis was performed on data from 61 women and 154 cycles.

Each woman in the study collected data in each cycle using subject device, Clearblue Digital Ovulation Test, and the Lady-Comp device (predicate).

The primary endpoint assessed the error in detecting the ovulation day using the Ava Fertility Tracker compared to urinary LH tests as a reference. In addition, the difference in the number of temperature shifts detected using basal-body temperature (Lady-Comp) compared to wrist skin temperature (Ava Fertility Tracker) was assessed as a secondary endpoint.

The study demonstrated that the Ava Fertility Tracker was able to accurately predict the day of ovulation. With a mean error of 0.315 days (95% CI -0.029 to 0.698) the Ava Fertility Tracker was within the limits of the equivalence bounds of ±2 days, showing that the device can predict the time ovulation as compared to the LH reference test (p-value for equivalence <0.001). Furthermore, the secondary endpoint outcome showed that the Ava Fertility Tracker detected significantly more post-ovulation temperature shifts compared to Lady-Comp (p<0.001).

Conclusion

Based on the non-clinical verification performance testing and the clinical validation provided with the submission, it can be concluded that the Ava Fertility Tracker is as safe and effective as the predicate device and supports a determination of substantial equivalence.

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