DEC 2 0 2011

K 102499

510(K) Summary

Submitter Information

Submitter's Name:	Cambridge Temperature Concepts Ltd
Address:	23 Cambridge Science Park
	Milton Road, Cambridge, CB4 0EY
	United Kingdom
Tel:	+44 1223 437 006
Fax:	+44 1223 437 008
US contact:	Scott R. Mackie (Founder Director (USA))
	Cambridge Temperature Concepts
	P.O. Box 390930, Cambridge, MA 02139
Tel:	+1 617 803 1026
Email:	scott@temperatureconcepts.com

Date summary prepared: 13th December 2011

Device information

Trade name:	DuoFertility
Common name:	Computerized Basal Body Temperature Thermometer
Classification name:	Device, fertility diagnostic, proceptive
Product Code:	LHD

Predicate devices

K021978 Nishitomo Co., Ltd. Petit Sophia

K050094 Lady-Comp USA. Lady-Comp

K033534 Mini-Mitter Co., Inc. VitalSense

Description of device

The DuoFertility system is a computerized basal body temperature thermometer with the following features:

1. A temperature Sensor with integrated data logger to monitor temperature throughout sleep and store the temperature readings
2. Measuring accuracy within +/- 0.05 deg C
3. Adhesive patches to hold the temperature Sensor against the users skin
4. Radiofrequency communications hardware to transmit the stored temperature data to a receiving device
5. Microprocessor based Reader to process and display temperature readings and fertility information.

Indication for Use

The DuoFertility Monitor is intended for measuring, and recording basal body temperature (BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

Predicate Device Comparison

DuoFertility is a Proceptive Diagnostic Fertility Device (Product Code LHD) so the primary predicate device is the Petit Sophia Fertility Monitor (K021978).

A second predicate device, the Lady-Comp computerized basal body temperature thermometer K050094), is also included as comparative clinical testing has been conducted with this device

The Indications for Use Statement of the DuoFertility Monitor is the same as the Petit Sophia and Lady-Comp predicate devices.

In all of the following key features of a fertility monitor, the DuoFertility Monitor is substantially equivalent to the Petit Sophia and Lady-Comp devices:

- Operating Principle - all devices use the Basal Body Temperature Method
- Temperature Sensor - all devices use a thermistor sensor
- Sensor Accuracy – all devices have an accuracy of +/- 0.05 degrees Centigrade
- User Inputs – all devices have the facility for user input of relevant data
- PC Display - both the DuoFertility Monitor and Petit Sophia devices have the facility for display of temperature graphs plus additional information on a computer.

The following are the new technological characteristics of the DuoFertility Monitor with respect to the Petit Sophia and Lady-Comp fertility monitors.

- Number of Sensors - The Petit Sophia and Lady-Comp fertility monitors use a single thermistor temperature Sensor whereas the DuoFertility Monitor uses 2 thermistors plus an accelerometer/movement Sensor. The additional Sensors do not raise any safety issues and are incorporated to improve effectiveness.
- Number of Measurements - The Petit Sophia and Lady-Comp fertility monitors record a single temperature measurement taken by the user soon after waking up whereas the DuoFertility Sensor logs measurements periodically, forming a time-series of movement, temperature and heat-flow data. These reduce many sources of systematic and random error and are utilised to improve effectiveness..
- Body worn Sensor - Body worn Sensor - The Petit Sophia and Lady-Comp monitors are only used for five minutes on waking up whereas the DuoFertility Sensor is attached to the body for extended periods (at least during periods of sleep). The benefit of the body worn sensor is that data is collected automatically with no need to perform a five minute temperature measurement immediately on waking. Automatic measurement reduces potential human error from the temperature measurement process.
- Location of Temperature Measurement - The Petit Sophia and Lady-Comp fertility monitors utilize oral temperature measurement whereas the DuoFertility Monitor utilizes axillary temperature measurement. Both oral and axillary are well established locations for body temperature measurement.

However DuoFertility has one additional technological characteristic, wireless communication of data from skin temperature Sensor, so a tertiary predicate device, the VitalSense Physiological Data Logging Device (K033534) is considered with regard to this characteristic.

The VitalSense Sensor continuously transmits the data to the data logger which must be within the 2 meter operating range whereas the DuoFertility Sensor only transmits the data when the user selects to do this by placing the Sensor on the Reader. Both the DuoFertility and VitalSense systems use wireless communication for transmission of temperature data from a skin sensor. The differences in the two transmission methods relate to specific features for the different applications. The DuoFertility Monitor has particular advantages for the fertility monitor application. The differences in the technological characteristics of the Sensor data communication do not raise any issues of safety or effectiveness.

The DuoFertility Monitor has identical Indications for Use Statement as the Petit Sophia and Lady-Comp devices and the new technological characteristics do not raise any issues of safety and effectiveness. It is therefore concluded that the DuoFertility Monitor is substantially equivalent to the existing marketed predicate devices.

<u>Non-clinical tests</u>

Cambridge Temperature Concepts has conducted the following non-clinical tests:

- Temperature measurement
  - 5 factory-calibrated Sensors were tested to determine the accuracy, precision and drift characteristics of Sensors for the DuoFertility system.
  - The test protocol comprised the following:

        - Expose to known temperatures, by immersion in a calibrated, computer-controlled waterbath, over the expected range of human body temperatures.
        - Expose to a known temperature at approximately human body temperature by immersion in a calibrated waterbath, to monitor drift over at least 24 hours.
    - The results demonstrate that the tested Sensors were within the required specification of ±0.05 degrees C for each of accuracy, drift and precision over a 24-hour period.

- Electro-magnetic compatibility
    - All EMC testing was conducted by an independent Test House
    - The DuoFertility System passed all applicable EMC emissions and immunity tests required by EN 60601-1-2:2002 (IEC 60601-1-2:2001) and the FCC requirements defined in 47 CFR 15.

- Electrical safety
    - The conformity assessment was conducted by an independent Test House
    - Assessment was conducted in accordance with EN 60601-1:1990 + Amendments Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988 + Amendments)
    - All safety tests passed (2 labeling issues corrected)

- Biocompatibility testing
    - The sensor and adhesives were tested by an accredited laboratory for cytotoxicity, maximization sensitization and primary skin irritation in accordance with the ISO 10993 family of standards including.
    - All tests showed the DuoFertility sensor and adhesive materials to be safe for use in the intended manner.

- Software
    - Software verification testing has demonstrated that the sensor, reader, PC and server software comply with the requirements of the Software Requirements Specification.

Clinical tests

Cambridge Temperature Concepts enrolled subjects in a clinical study to collect data comparing temperature readings measured with DuoFertility compared to the Lady-Comp predicate device. Subjects included women who were not familiar with the device and relied on instructions provided in the device labelling. Analysis of data from 21 menstrual cycles demonstrated that the DuoFertility monitor is at least equivalent in performance to the Lady-Comp predicate device for the purpose of identifying the date of ovulation. The study also provided evidence that users are able to follow the instructions and use the device as intended.

Conclusion regarding safety and effectiveness

Comparison of the intended use and technological characteristics with the predicate devices and the results of non-clinical and clinical tests demonstrate that the DuoFertility system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott Mackie
Founder Director
Cambridge Temperature Concepts Ltd.
P.O. Box 390930
CAMBRIDGE MA 02139

DEC 2 0 2011

Re: K102499
Trade/Device Name: DuoFertility
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LHD
Dated: December 7, 2011
Received: December 13, 2011

Dear Mr. Mackie:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102499

Device Name: DuoFertility

Indications for Use:

The DuoFertility Monitor is intended for measuring, and recording basal body temperature (BBT) as an aid in ovulation prediction to aid in conception (not to be used for contraception).

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102499