510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DATE:	July 30, 2013
APPLICANT:	Fertility Focus Ltd. Robert Milnes, CEO Unit 19D, University of Warwick Science Park Warwick Technology Park, Gallows Hill Warwick, United Kingdom CV34 6UW Tel: 044-1494-510272 Email: robert.milnes@fertility-focus.com
OFFICIAL CORRESPONDENT FOR THIS SUBMISSION:	Penny Northcutt, RAC, FRAPS, CQA Regulatory Consultant for Fertility Focus REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 Email: pennynorthcutt@theregsolutions.com
TRADE NAME:	Fertility Focus OvuSense Fertility Monitor
CLASSIFICATION NAME:	Device, fertility diagnostic, proceptive
DEVICE CLASSIFICATION AND PRODUCT CODE:	Pre-amendment, Unclassified Product Code: LHD
PREDICATE DEVICE NAME:	DuoFertility Monitor, K102499 Bioself 2000 Fertility Indicator, K904211

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SUBSTANTIAL EQUIVALENCE:
The Fertility Focus OvuSense Fertility Monitor is substantially equivalent to the legally marketed DuoFertility Monitor (K102499) and the Bioself 2000 Fertility Indicator (K904211). The Fertility Focus OvuSense Fertility Monitor has similar indications for use statements, principles of operation, and technological characteristics as the predicate devices.

DESCRIPTION OF THE DEVICE:
The Fertility Focus OvuSense Fertility Monitor is intended for measuring and recording core body temperature intra-vaginally on a nightly basis during the non-menstruating phases of the monthly female reproductive cycle. The Fertility Focus OvuSense Fertility Monitor consists of two components made of silicone - a Personal Sensor, which collects the data, and a Reader (with LCD display), which establishes a communication link to the Personal Sensor whereupon the data is transferred to the Reader.

Electromagnetic induction communications hardware transmits the stored temperature data from the Personal Sensor to the receiving device, the Reader, activated when the Sensor is placed on the Reader cradle and the Reader's dedicated download button is pressed. The microprocessor based Reader filters the overnight data, then calculates and stores the 25th percentile value, representative of the average basal (lowest) overnight temperature.

The Reader then displays these nightly temperature readings on a graph using a relative scale – the key information for necessary calculations being the temperature changes relative to other recorded temperatures within a cycle for a particular user, and not absolute temperature value. At the start of the next cycle, indicated by the User inputting first day of the bleeding in the cycle, the Reader algorithm calculates the date of ovulation in the prior cycle, and uses this to predict the fertile period for the cycle which has just started. The Reader then displays fertility information in a verbal summary, including:

- An indication of the day ovulation occurred in the prior cycle, or if ovulation was not detected it displays this information instead.
- An indication whether the cycle length was within the expected normal parameters.

INTENDED USE/INDICATIONS FOR USE:
The Fertility Focus OvuSense Fertility Monitor (Fertility Focus OvuSense Fertility Monitor Starter Kit M009-US, which includes Reader M010-US and Personal Sensor M011) 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).

TECHNOLOGICAL CHARACTERISTICS:
OvuSense Fertility Monitor and DuoFertility Monitor have the following similar and substantially equivalent technological characteristics:

- Operating Principle – Both devices assess Basal Body Temperature.
- Temperature Sensor – Both devices use a thermistor sensor.
- Sensor Accuracy – The DuoFertility device has a quoted accuracy of +/- 0.05 degrees Centigrade, and of +/- 0.1 degrees Celsius; OvuSense Fertility Monitor has an accuracy of +/- 0.05 degrees Centigrade. Any potential difference in the accuracy of temperature measurements is not believed to raise any issues of safety, and is a function of the requirements of each devices' algorithms.
- User Inputs – Both devices have the facility for user input of relevant data.
- Display of Graphs – Both devices have the facility for the display of temperature graphs. The DuoFertility device uses a computer for this display and uses an absolute temperature scale, whilst OvuSense Fertility Monitor uses the OvuSense Reader for

display and a relative temperature scale. The different display methodologies do not raise any safety issues, with the relative temperature scale allowing the OvuSense Fertility Monitor user a graph view optimized to their particular temperature readings.

- Number of Measurements – Both devices record multiple temperatures. The difference in any relative number of temperature measurements is not believed to raise any issues of safety, and is simply a function of the requirements of each devices' algorithms.
- Automatic measurements – Both devices take measurements automatically.
- Wireless transfer of data – Both devices involve the transfer of data from the Sensor to a receiving unit.
- Algorithm – Both devices use an algorithm to calculate the date of ovulation. The additional information provided by the OvuSense Fertility Monitor device in respect of absence of ovulation and fertile period prediction is not believed to raise any direct issues of safety, and is employed for increased effectiveness.

The following differences between DuoFertility and OvuSense Fertility Monitor are noted and thus a secondary predicate or reference device – Bioself 2000 is used for substantial equivalence purposes.

- Number of Thermistors – The DuoFertility device uses two thermistors plus an accelerometer/movement Sensor; the OvuSense Fertility Monitor device uses a single thermistor. The Bioself 2000 device uses a single thermistor.
- Location of Thermistor – The DuoFertility device is worn on the skin; the OvuSense device is placed intravaginally by means of a Personal Sensor. The Bioself 2000 device can be used intravaginally or orally.

The use of two thermistors and an accelerometer (in DuoFertility) versus the use of a single thermistor (OvuSense Fertility Monitor and Bioself 2000) is not believed to raise any direct issues of safety or effectiveness, and the relative location of vaginal versus skin placement is employed by OvuSense Fertility Monitor and Bioself 2000.

NONCLINICAL PERFORMANCE TESTING:
A series of performance tests was conducted in support of the design verification of the Fertility Focus OvuSense Fertility Monitor.

Summary of Performance Testing Conducted on OvuSense	
Biocompatibility	In Vitro Cytotoxicity MEM Elution Assay
	Mucosal (Vaginal) Irritation Test
	Guinea Pig Maximization Sensitization Test
	USP Physicochemical Extraction Parameters
	ISO Acute Systemic Toxicity Test
	In Vitro Mouse Micronucleus Assay – 2 Extracts (ISO)
	In Vivo Mouse Micronucleus Assay – 2 Extracts
	Bacterial Mutagenicity Test (Ames Assay)

Summary of Performance Testing Conducted on OvuSense	
	Subchronic (14 day) Intravenous Toxicity Study in Non-Swiss Webster Mice (14 Repeat Dose Exposure)(GLP)
	Subacute (14 day) Intraperitoneal Toxicity Study in Non-Swiss Webster Mice (14 Repeat Dose Exposure) (GLP)
	Exhaustive Extractables
Electrical Testing	EN60601-1-4:2000 Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for electrical programmable medical systems.
	EN60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
	EN301 489-3 v1.4.1 Electromagnetic Compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 3: Specific Conditions for Short-Range Devices (SRD) Operating on Frequencies between 9 KHz and 40 GHz
	IEC60601-1:2006 Medical equipment. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN302 291 v1.1.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Close Range Inductive Data Communication equipment operating at 13,56 MHz; Part 2: Harmonized EN under article 3.2 of the R&TTE Directive
Mechanical Testing	Tensile (Pull Test)
Design Verification & Validation	Physical Dimensions, User Cleaning, Reliability for Operating Life, Human Factors-Machine Interface
Cleaning Validation	Cleaning Validation of Personal Sensor

CLINICAL TESTING:
Clinical investigation was conducted of the Fertility Focus OvuSense Fertility Monitor from 19 women who participated in a prospective study measuring 81 cycles over 3 months participation.

The data from the primary endpoint of the trial described in the CIP demonstrated that the OvuSense Fertility Monitor system of ovulation detection provided a biological and statistically significant improvement in ovulation detection compared with the traditional method of oral temperature measurement. It demonstrated good linear agreement with the gold standard detection of ovulation using ultra-sound and an improved 95% confidence interval for the agreement.

CONCLUSION:

Based on the nonclinical verification performance testing and clinical validation, it can be concluded that the Fertility Focus OvuSense Fertility Monitor is equivalent to the DuoFertility Monitor (K102499) and Bioself 2000 (K904211) with respect to intended use, principles of operation, and technological characteristics. The Fertility Focus OvuSense Fertility Monitor has been demonstrated to be as safe, as effective, and performs as well as or better than the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 6, 2013

Fertility Focus, Ltd.
% Penny Northcutt, RAC, FRAPS, CQA
President/CEO
REGSolutions, LLC
717 Lakeglen Drive
Suwanee, GA 30024

Re: K122337
Trade/Device Name: Fertility Focus OvuSense Fertility Monitor
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LHD
Dated: July 30, 2013
Received: July 31, 2013

Dear Penny Northcutt,

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 contact 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. 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,

Glenn B. Bell -S

for Benjamin R. Fisher, Ph.D.
Director
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 (if known): K122337

Device Name: **Fertility Focus OvuSense Fertility Monitor**

Indications for Use:

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

Glenn B. Bell -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122337