SEP 23 2002

K020808

510(k) Summary

I. General Information on Submitter

Pheromone Sciences Corporation
443 King Street East
Toronto, Ontario, Canada
M5A 1L5
Telephone: (416) 861-9854

II. General Information on Device

Proprietary Name:	Fertilité OV™
Common Name:	PSC Fertility Monitor
Classification Name:	Device, Fertility, Diagnostic, Proceptive

III. Predicate Devices

Clear Plan Easy Fertility Monitor (Unpath Ltd.)	K981207
Cue Fertility Monitor (Zetec Inc.)	K850579
Tycoyf Fertility Software (Ovusoft Inc.)	K002726

IV. Device Description

The PSC Fertility Monitor consists of a small wristwatch that houses an interactive microprocessor and a biochemical sensor. The device measures chloride ion levels in female sweat from the skin surface in order to predict current fertility status by displaying the result on the screen. The device provides the user with notice up to four days before ovulation during which the user may have the greatest chance of becoming pregnant.

V. Intended Uses

The PSC Fertility Monitor is an over-the-counter ("OTC") *in vitro* diagnostic ("IVD") device. It is intended to be used by women as an aid in conception by measuring hormone-induced changes in the composition of the perspiration on the skin during menstrual cycle. Properly used, it gives more notice for conceiving and is not invasive. It is NOT to be used for contraception.

VI. Technological Characteristics of the Device Compared to Predicate Devices

The technological characteristics of the PSC Fertility Monitor are identical to those of the listed predicate devices, with the exception of the fact that the PSC Fertility Monitor measures changes in chloride ion levels in female sweat.

VII. Summary of Safety and Effectiveness Data

No hazards were identified when ANSI/AMMI/ISO 14971:200 Application of Risk Management To Medical Devices was applied to the PSC Fertility Monitor.

A non-randomized, prospective clinical study was conducted to assess the clinical usefulness of the PSC Fertility Monitor as a non-invasive method of predicting impending ovulation in women. A total of 100 female research participants were chosen for comparisons of three fertility monitors, including the PSC Fertility Monitor. Each device measured changes of different parameters – basal body temperature ("BBT"), chloride ion concentrations, and lutenizing hormone ("LH") levels in urine – and were compared to serum LH levels. Data from the clinical study showed that the PSC Fertility Monitor predicted ovulation better than basal body temperature ("BBT"), which is the basis for several legally marketed fertility monitors, and almost as well as LH levels in urine, which is the basis for several legally marketed fertility monitors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Pheromone Sciences Corp.
c/o Mr. Larry R. Pilot
McKenna, Long & Aldrich, LLP
1900 K Street, NW
WASHINGTON DC 20006

Re: K020808
Trade/Device Name: Fertilité OV™ (PCS Fertility Monitor)
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LHD
Dated: June 27, 2002
Received: June 27, 2002

Dear Mr. Pilot:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K026808

510(k) Number:

Device Name: Fertilité OV™ (PSC Fertility Monitor)

Indications for Use:

Fertilité OV™ (PSC Fertility Monitor) is an over-the-counter ("OTC") *in vitro* diagnostic ("IVD") device intended for use by women as an aid in conception by measuring hormone-induced changes in the composition of the perspiration on the skin during the menstrual cycle. Properly used, it gives more notice for conceiving and is not invasive. It is NOT to be used for contraception.

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K026808

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation ("ODE")

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 C.F.R. 801.109)