DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 1998

Terry R. Knapp, M.D.
President and Medical Director
Conception Technology, Inc.
214 S. College Avenue
Ft. Collins, CO 80524

Re: K973860
Ovulon Monitor
Dated: October 7, 1997
Received: October 9, 1997
Regulatory Class: I
Unclassified/Procode: 85 LHD

Dear Dr. Knapp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION II: INDICATIONS FOR USE

510(k) Number (if known): K973860

Device Name: Ovulon Monitor

Indications for Use:

The Ovulon Monitor is a fertility aid intended for over-the-counter purchase. It is an electronic biosensor designed for home use that yields digital information (data points) relative to electron flow in the extracellular milieu of the posterior fornix and paracervical region of the vagina.

The Ovulon Monitor is intended for daily use in normally cycling (i.e., regularly menstruating and, presumably, ovulating) healthy females who may desire to achieve pregnancy (conception). Much as a basal body temperature thermometer or a home urine LH kit, the Ovulon Monitor serves as an independent information aid to the woman by helping to define the fertile window near the midpoint of each monthly cycle, whereby she may choose the proper timing for vaginal intercourse. If the user chooses the guidance of a physician for fertility treatment, the Ovulon Monitor may serve to provide the user and her physician with data to better time artificial insemination or other interventional techniques.

The Ovulon Monitor is to be used as an aid to conception and is not to be used for contraception.

After six (6) or more cycles, if the user is not successful in achieving conception, she should consult her physician.

(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, Abdominal, ENT, and Radiological Devices
510(k) Number K973860

Prescription Use ______ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)