DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 24 1999

Louise Roberts
Regulatory Affairs Manager
Unipath Limited
Priory Business Park
Bedford
MK44 3UP
United Kingdom

Re: K990223
Trade Name: Modification of Clearplan Easy Fertility Monitor
Regulatory Class: I
Product Code: LHD, CEP
Dated: January 19, 1999
Received: January 25, 1999

Dear Ms. Roberts:

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 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). 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 requirements, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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) 594-4588. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K990223/A1

FDA/CDRH/ODE/DMC

FEB 8 4 08 PM '99

510(k) NUMBER (IF KNOWN) K990223

RECEIVED

DEVICE NAME: MODIFICATION OF THE CLEARPLAN EASY FERTILITY MONITOR

INDICATIONS FOR USE:

The CLEARPLAN EASY FERTILITY MONITOR, an over-the-counter (OTC) in vitro diagnostic device, is intended to be used by women as an aid to conception by identifying those days in a woman's cycle on which intercourse is most likely to lead to conception via a urine test. The device consists of a software-controlled electronic monitor and packs of test sticks. The product will be made available to the consumer through pharmacies and drug stores.

The CLEARPLAN DATA TRANSFER SYSTEM is an accessory to the CLEARPLAN EASY FERTILITY MONITOR which allows the information collected by this product to be transferred to and stored on a computer, and viewed on the computer display or printed. The CLEARPLAN DATA TRANSFER SYSTEM also allows the time of acts of intercourse to be recorded electronically and the data to be collated on the computer with the information collected by the CLEARPLAN EASY FERTILITY MONITOR.

The CLEARPLAN DATA TRANSFER SYSTEM consists of a software controlled electronic card reader, a personal computer software package, electronic memory cards and user instructions.

The target market for the CLEARPLAN DATA TRANSFER SYSTEM is women who have purchased the CLEARPLAN EASY FERTILITY MONITOR. In addition the device will be of use to Obstetricians, Gynaecologists and Fertility Specialists.

The CLEARPLAN DATA TRANSFER SYSTEM is intended to be used to transfer data which have already been collected by the the CLEARPLAN EASY FERTILITY MONITOR to a computer. The information which is presented to the user of the device is limited to that which the they could have recorded on paper on a daily basis by noting the indications given by the CLEARPLAN EASY FERTILITY MONITOR and the user's own activities. Therefore the CLEARPLAN DATA TRANSFER SYSTEM does not affect the intended use of the CLEARPLAN EASY FERTILITY MONITOR or the fundamental scientific technology of the CLEARPLAN EASY FERTILITY MONITOR.

(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 Clinical Laboratory Devices
510(k) Number K990223

Prescription Use _____ OR Over-The-Counter-Use ✓
(Per 21 CFR 801.109) (Optional Format 1-2-