DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 7 1998

Dr. Borek Janik
Official Correspondent/SEBIA
C/O Morax
13805 Waterloo
Chelsea, Michigan 48118

Re: K974854
HYDRAGEL LIPO Kits
Regulatory Class: I
Product Code: JHO
Dated: July 24, 1997
Received: July 27, 1998

Dear Dr. Janik:

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 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 (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

510(k) Number (if known): K974854

Device name: HYDRAGEL-MINI LIPO Kit - PN 4093
HYDRAGEL LIPO Kit - PN 4007
HYDRAGEL LIPO MAXI Kit - PN 4207
HYDRAGEL 7 LIPO Kit - PN 4104
HYDRAGEL 15/30 LIPO Kit - PN 4124

Indications For Use:

The HYDRAGEL-MINI LIPO, HYDRAGEL LIPO, HYDRAGEL LIPO MAXI, HYDRAGEL 7 LIPO, and HYDRAGEL 15/30 LIPO kits are designed for determination of lipoprotein profiles in human serum.
All HYDRAGEL LIPO kits utilize the same composition of alkaline buffered HYDRAGEL LIPO agarose gels, same reagents and the same procedure. The only differences among the individual kits are the number of samples per gel and that some kits are for the manual and some for the automated format:
The HYDRAGEL-MINI LIPO , HYDRAGEL LIPO and HYDRAGEL LIPO MAXI kits are designed for use with a manual electrophoresis apparatus. These kits are intended to run up to 5, 8 and 10 samples per gel, respectively.
The HYDRAGEL 7 LIPO and HYDRAGEL 15/30 LIPO kits are designed for use with the semi-automated Hydrasys electrophoresis apparatus. These kits are intended to run up to 7, 15 and 30 samples per gel, respectively.

The resulting electrophoregrams can be evaluated visually for pattern abnormalities or by densitometry to obtain approximate, relative quantification of individual zones. Fredrickson classification of lipoproteins aids in the interpretation of lipoprotein patterns. Indication of the qualitative (presence of abnormal or absence of normal fractions) or semi-quantitative (relative increase or decrease of fractions) abnormalities necessitates further lipoprotein analyses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(for AW Montgomery)
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____

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

(Optional Format 1-2-96)