DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 1999

Dr. Borek Janik
Official Correspondent
Morax
13805 Waterloo Road
Chelsea, Michigan 48118

Re: K990250
Trade Name: Hydragel LDL/HDL Chol Direct
Hydragel 7 LDL/HDL Chol Direct
Hydragel LDL/HDL Chol Direct 15/30
Regulatory Class: I Reserved, Class I, Class I
Product Code: LBT, LBS, JHO
Dated: April 13, 1999
Received: April 19, 1999

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 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/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): K990250 ~~K972015~~

Device name:		
	HYDRAGEL LDL/HDL CHOL DIRECT	PN 4005
	HYDRAGEL 7 LDL/HDL CHOL DIRECT	PN 4103
	HYDRAGEL LDL/HDL CHOL DIRECT 15/30	PN 4123

Indications For Use:

HYDRAGEL LDL/HDL CHOL DIRECT, HYDRAGEL 7 LDL/HDL CHOL DIRECT and HYDRAGEL LDL/HDL CHOL DIRECT 15/30 kits are designed for quantification of the cholesterol carried by the LDL and HDL lipoprotein fractions of human plasma or serum. The analysis is performed in two stages:

- electrophoresis on agarose gel to separate the VLDL, LDL and HDL as well as chylomicrons and Lp (a) when present,
- visualization of lipoprotein fractions based on a sensitive and cholesterol-specific enzymatic method involving cholesterol esterase and cholesterol oxidase, and a chromogenic system with reduced AEC (amino ethyl carbazole) and peroxidase.

The stained electrophoregrams are intended for visual interpretation to confirm identification of the individual fractions and for densitometry to obtain accurate, relative concentrations of cholesterol in the individual lipoprotein fractions If the sample's total cholesterol value is known, cholesterol distribution in g/dL or mol/L concentrations can be calculated. Since the LDL cholesterol and HDL cholesterol assays are of primary interest, laboratories may chose to measure the relative concentration of cholesterol only in the HDL and LDL fractions.

The procedure is indicated for the general population for a direct measurement of:

- the LDL cholesterol level regardless the triglyceride levels
- the HDL cholesterol level
- the ratio LDL/HDL cholesterol

The HYDRAGEL LDL/HDL CHOL Direct kit is designed for use with a manual electrophoresis apparatus. The kit is intended to run up to 8 samples per gel.

The HYDRAGEL 7 LDL/HDL CHOL Direct and HYDRAGEL LDL/HDL CHOL Direct 15/30 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.

(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 K990250

See Revised

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