



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 17 2002

Borek Janik, Ph.D.
Official Correspondent
Morax
13805 Waterloo
Chelsea, MI 48118

Re: k012789
Trade/Device Name: HYDRAGEL LDL/HDL CHOL Direct K20 PN 3005
HYDRAGEL 7 LDL/HDL CHOL Direct PN 4109
HYDRAGEL LDL/HDL CHOL Direct 15/30 PN 4129
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: JHO
Dated: December 21, 2001
Received: December 27, 2001

Dear Dr. Janik:

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 such 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.

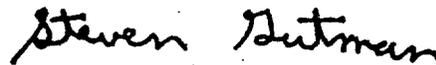
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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" (21CFR 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,



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

K012789

510(k) Number (if known): Special 510(k): Device Modification

Device name:	HYDRAGEL LDL/HDL CHOL Direct K20	PN 3005
	HYDRAGEL 7 LDL/HDL CHOL Direct	PN 4109
	HYDRAGEL LDL/HDL CHOL Direct 15/30	PN 4129

Indications For Use:

HYDRAGEL LDL/HDL CHOL Direct K20, 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 Low Density Lipoprotein (LDL) and High Density Lipoprotein (HDL) fractions of human serum. The analysis is performed in two stages:

- electrophoresis on agarose gel to separate the VLDL, LDL and HDL as well as chylomicrons,
- visualization of lipoprotein fractions based on a sensitive and cholesterol-specific enzymatic procedure involving the cholesterol esterase / cholesterol dehydrogenase system coupled with nitro blue tetrazolium chromogen.

The stained electrophoregrams are intended for visual interpretation to confirm identification of the individual fractions and for densitometry to obtain relative concentrations of cholesterol in the individual lipoprotein fractions. When the sample's total cholesterol value is known, cholesterol distribution in g/dL or mol/L concentrations can be calculated.

The test system is intended for the measurement of the LDL cholesterol and HDL cholesterol. The cholesterol values of only these two fractions are indicated as an aid in the diagnosis and treatment of lipid disorders.

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 K20 kit is designed for use with a manual electrophoresis apparatus, K20. The kit is intended to run up to 7 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)

Jean Cooper
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K012789

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use

(Optional Format 1-2-96)