DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

MAR - 4 1998

Re: K972591/S1
Trade Name: HYDRAGEL BENCE JONES KIT/ MAXI KIT HYDRAGEL BENCE JONES/ HYDRAGEL 2 BENCE JONES KIT/ HYDRAGEL 4 BENCE JONES KIT
Regulatory Class: II
Product Code: JKM
Dated: January 5, 1998
Received: January 6, 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 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.

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

510(k) Number (if known): K972591

Device name: HYDRAGEL BENCE JONES Kit
MAXI KIT HYDRAGEL BENCE JONES
HYDRAGEL 2 BENCE JONES Kit
HYDRAGEL 4 BENCE JONES Kit

Indications For Use:

HYDRAGEL BENCE JONES, MAXI KIT HYDRAGEL BENCE JONES, HYDRAGEL 2 BENCE JONES and HYDRAGEL 4 BENCE JONES kits are designed for qualitative detection and identification of Bence Jones proteins (monoclonal free light chains) in urine and serum. The detection of Bence Jones proteins serves as a qualitative aid in the identification of monoclonal gammopathies.

The analysis is generally performed on unconcentrated urine or on diluted serum. All these kits utilize the same composition of alkaline buffered HYDRAGEL BENCE JONES agarose gels and the same procedure which is carried out in two stages:
• electrophoresis of the sample on multi-track agarose gel to separate the individual urinary or serum proteins,
• the separated proteins in the reference track are fixed, the remaining tracks are subjected to respective immunofixation with anti alpha, gamma & mu heavy chain trivalent antiserum, anti kappa and anti lambda free & bound light chains antisera; anti kappa and anti lambda free light chains antisera. The fixed and immunoprecipitated proteins are then stained with acid violet. The electrophoregrams are evaluated visually. The suspect band (in the reference track) is identified from the positive reaction, or lack of, with the individual antisera.

The HYDRAGEL BENCE JONES kit and MAXI KIT HYDRAGEL BENCE JONES are designed for use with a manual electrophoresis apparatus. The only difference between these two kits is the total number of tests which can be performed with each kit, i.e., 10 and 100, respectively.
Each agarose gel in the HYDRAGEL BENCE JONES kit and MAXI-KIT HYDRAGEL BENCE JONES is intended to run one sample.

The HYDRAGEL 2 BENCE JONES and HYDRAGEL 4 BENCE JONES kits are designed for use with the semi-automated Hydrasys electrophoresis apparatus.
Each agarose gel in the HYDRAGEL 2 BENCE JONES and HYDRAGEL 4 BENCE JONES kits is intended to run two and four samples, respectively.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices K972591
510(k) Number _____

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

(Optional Format 1-2-96)