DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 21 1999

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

Re: K991362
Trade Name: HYDRAGEL Hemoglobin (E), Mini Hemoglobin (E), 7 Hemoglobin (E), 15 Hemoglobin (E), Acid (E) Hemoglobin (E), Mini Acid (E) Hemoglobin (E), 7 Acid (E) Hemoglobin (E), and 15 Acid (E) Hemoglobin (E)
Regulatory Class: II
Product Code: JBD, GKA, GIQ, KQI, MLL
Dated: April 9, 1999
Received: April 14, 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): K991362

Device name: HYDRAGEL HEMOGLOBIN(E)
HYDRAGEL - MINI HEMOGLOBIN(E)
HYDRAGEL 7 HEMOGLOBIN(E)
HYDRAGEL 15 HEMOGLOBIN(E)
HYDRAGEL ACID(E) HEMOGLOBIN(E)
HYDRAGEL - MINI ACID(E) HEMOGLOBIN(E)
HYDRAGEL 7 ACID(E) HEMOGLOBIN(E)
HYDRAGEL 15 ACID(E) HEMOGLOBIN(E)

Indications For Use:

Sebia's HYDRAGEL HEMOGLOBIN(E) and HYDRAGEL ACID(E) HEMOGLOBIN(E) lines of devices are intended as an aid in the detection and identification of human hemoglobin abnormalities, namely hemoglobinopathies (structural hemoglobin abnormalities) and thalassemias (regulation abnormalities). The uses are indicated as follows:

The HYDRAGEL HEMOGLOBIN(E) and HYDRAGEL MINI HEMOGLOBIN(E) Kits are designed for use in conjunction with a manual electrophoretic apparatus. **The HYDRAGEL 7/15 HEMOGLOBIN(E) Kits** are designed for use with the semi-automated HYDRASYS electrophoretic apparatus. All these kits utilize alkaline agarose gels for electrophoretic separation of human hemoglobins. The electrophoregrams are interpreted visually for pattern abnormalities. Densitometry can serve as an aid in the interpretation by providing relative concentrations of individual fractions. The kits are intended for the detection of the normal hemoglobins (A and A_2) and the major hemoglobin variants S or D and C or E. They are indicated for screening for clinically important abnormal hemoglobins. Electrophoresis on acidic gel, e.g., HYDRAGEL ACID(E) HEMOGLOBIN(E), should follow to confirm the identification of hemoglobin variants, in particular, to differentiate hemoglobins S from D and E from C.

The HYDRAGEL ACID(E) HEMOGLOBIN(E) and HYDRAGEL MINI ACID(E) HEMOGLOBIN(E) Kits are designed for use in conjunction with a manual electrophoretic apparatus. **The HYDRAGEL 7/15 ACID(E) HEMOGLOBIN(E) Kits** are designed for use with the semi-automated HYDRASYS electrophoretic apparatus. All these kits utilize acid buffered agarose gels for electrophoretic separation of human hemoglobins. The electrophoregrams serve for qualitative, visual interpretation of the patterns. The kits are indicated for confirming the identity of clinically important abnormal hemoglobins that have been previously detected on alkaline buffered HYDRAGEL HEMOGLOBIN(E) gels. Primarily, they serve for differentiation of hemoglobins S from D and E from C.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia C. Markin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991362

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

(Optional Format 1-2-96)