NOV 30 1999

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K993496 ."

For any questions contact:

James D. Lapicola
524 Stone Road
Benicia, CA 94510
(707) 746-7833 ext. 208
FAX: (707) 746-7837

Date Prepared: October 11, 1999

Gentlemen:

Following is a summary of the basis for a substantially equivalent determination:

Trade or proprietary name,	Retic-Quinox
Common or usual name	Reticulocyte Control Mixture
Classification name	Mixture, Hematology Quality Control
Product Code 81JPK	
CFR Section 21 CFR 864.8625	
Device Class II	
Hematology Classification Panel	

Predicate Device Information:

Trade or proprietary name,	Retic-C manufactured by Coulter Diagnostics
Common or usual name	Reticulocyte Control Mixture
Classification name	Mixture, Hematology Quality Control

510(K) Number: K930119
Approval Date: 4/5/93
21CFR864.8625, Hematology Quality Control Mixture
Product Code JPK
Hematology Panel

Device Description:

Retic-Quinox is a reference control material designed to monitor the accuracy and precision of Coulter instruments capable of performing reticulocyte counts.

Technological Characteristic Comparison

Both Coulter's Retic-C and Hematronix' Retic-Quinox are in vitro diagnostic controls composed of stabilized human red cells in combination with a reticulocyte-like component suspended in a buffered, bacteriostatic and fungistatic fluid. In both products, the reticulocyte-like component is a cell of similar size to a human red cell and which contains a nucleus. In both products, three levels are provided in order to better monitor the Coulter instrument's accuracy and precision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 30 1999

Mr. James D. Lapicola
Executive Vice President
Hematronix, Inc.
524 Stone Road
Suite A
Benicia, California 94510

Re: K993496
Trade Name: Retic-Quinox
Regulatory Class: II
Product Code: JPK
Dated: October 11, 1999
Received: October 15, 1999

Dear Mr. Lapicola:

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 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 993496

Device Name: Retic-Quinox

Indications For Use:

Retic-Quinox is a whole blood reference control material designed to monitor the accuracy and precision of Coulter instruments equipped with reticulocye measuring capabilities using VCS technology.

(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 K993496

✓ Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____