

AUG 15 1997

510(k) Summary

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

Date Prepared: July 18, 1997

Gentlemen:

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

Hematronix Product	
Trade Name	qUAntify
Common Name	Clinical Chemistry Urine Control
Classification Name	Quality Control Material per 21CFR862.1660

Substantially Equivalent Device: Kenlor Liquid Urine  
Control see 510(k)  
#K890577

Please note: qUAntify is currently "manufactured for"  
HEMATRONIX, INC. by Kenlor Industries. It is  
our intention to manufacture the material  
ourselves.

Device Description/INTENDED USE

The Hematronix qUAntify™ Control System is a liquid, ready-to-use, urine dipstick control. No reconstitution or dilution is required. The control is prepared from human source material and predetermined chemicals.

Controls evaluate the quality of day-to-day test performance. The qUAntify Control System is used to determine accuracy and precision in the measurement of the physical and chemical tests commonly employed in semiquantitative urine dipstick testing. Alternative tests such as the Glucose (Clinites), Bilirubin (Ictotest) and Ketone (Acetest) are also assayed. This control can be used to quality control the specified urine hCG tests. Two distinct levels are included to verify the recovery of normal and elevated patient values.

## Technological Characteristic Comparison

Both Kenlor's Liquid Urine Control and Hematronix' qUAntify are prepared from human source materials and predetermined chemicals. Two distinct levels are provided to verify the recovery of normal and elevated patient values.

## Equivalency between qUAntify and Kenlor Liquid Urine Control

	<u>qUAntify</u> (Applicant)	<u>Liquid Urine Control</u> (Kenlor)
Intended Use:	To monitor the precision system for the analytes listed.	To monitor the precision system for the analytes listed.
Measurement Technique:	Semiquantitative testing and assays	Semiquantitative testing and assays
Analytes:	Specific Gravity pH Leukocytes Nitrite Protein Glucose Ketones Urobilinogen Bilirubin Hemoglobin HCG	Specific Gravity pH Leukocytes Nitrite Protein Glucose Ketones Urobilinogen Bilirubin Hemoglobin HCG
Number of Common Analytes:	11	11
Matrix:	Human Source Materials and predetermined chemicals	Human Source Materials and predetermined chemicals
Stability:	Unopened Vial 2 years at 2°-8°C  Opened Vial 30 days at room temp.	Unopened Vial 2 years at 2°-8°C  Opened Vial 30 days at room temp.

Non Clinical Performance Data - Conclusions

qUAntify was evaluated on several instruments for all 11 analytes. The ranges observed were compared to published ranges for the same analytes in package inserts provided with Kenlor's Liquid Urine Control. The ranges were substantially equivalent. The data is summarized in the following table.

Equivalency Ranges as measures of Precision.

qUAntify mfg by HEMATRONIX, INC.		Liquid Urine Control mfg by Kenlor
Level I (Normal):		
Specific Gravity	1.020 ±.005	1.010 ±.005
pH	6 ±.5	5.5 ±.5
Level II (Abnormal):		
Specific Gravity	1.010-1.015	1.005-1.015
pH	8	7-8
Leukocytes	++	+
Nitrite	+	+
Protein	100	100
Glucose	250-500	250-350
Ketones	++	++
Urobilinogen	1-8	1-4
Bilirubin	++	+++
Hemoglobin	250	250
HCG	+	+

Safety and Effectiveness Conclusions:

Safety - qUAntify and Kenlor's MSDS list: 1) sodium azide acts as a constituent (0.05%); and 2) Human blood and blood products which is potentially biohazardous material. Each blood donor, however, is tested by FDA approved methods for HIV, HCV and HBs Ag.

Effectiveness - As seen in the Non Clinical Performance Data section above, the qUAntify control system will evaluate the quality of day-to-day test performance when used to determine accuracy and precision in the measurement of the physical and chemical tests commonly employed in semi-quantitative urine dipstick testing.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. James D. Lopicola  
Executive Vice President  
Hematronix, Inc.  
524 Stone Road  
Benicia, CA 94510

AUG 15 1997

Re: K972710  
qUANTify  
Regulatory Class: I  
Product Code: JJW  
Dated: July 18, 1997  
Received: July 21, 1997

Dear Mr. Lopicola:

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.

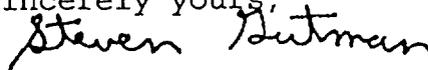
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

10(k) Number (if known): \_\_\_\_\_

Device Name: qUAntify

**Indications For Use:**

The Hematronix qUAntify TM Control System is a liquid, ready-to-use urine dipstick control. No reconstitution or dilution is required. The control is prepared from human source material and predetermined chemicals.

Controls evaluate the quality of day-to-day test performance. The qUAntify Control system is used to determine accuracy and precision in the measurement of the physical and chemical tests commonly employed in semiquantitative urine dipstick testing. Alternative tests such as the Glucose (Clinites), Bilirubin (Ictotest) and Ketone (Acetest) are also assayed. This control can be used to quality control the specified urine hCG tests. Two distinct levels are included to verify the recovery of normal and elevated patient values.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Clinical Laboratory Devices  
number 12972710

Prescription Use                        
(per 21 CFR 801.109)

OR

Over-The-Counter Use