K042641

JAN - 7 2005

CENOGENICS CORPORATION
100 ROUTE 520
MORGANVILLE, NJ 07751
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inquiry@cenogenics.com

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Proprietary name: CHEMVIEW-10™ Urinalysis Test Strips for urobilinogen, glucose, ketones, bilirubin, protein, nitrite, pH, occult blood, specific gravity and leukocytes.

Common name: Reagent test strip for urinalysis.

Classification: 21CFR 2900, Class I

Classification number: 75KQO

Establishment: Cenogenics Corporation
100 Route 520
Morganville, New Jersey 07751

Contact: Nitza Katz
Vice President

CHEMVIEW-10™ is a visual qualitative and semi-quantitative test for the determination of urobilinogen, glucose, ketones, bilirubin, protein, nitrite, pH, blood, specific gravity and leukocytes in urine.

Comparison studies were conducted at three reference laboratories. Fresh Urine specimens submitted to the laboratories for urinalysis as well as spiked urine specimens were tested simultaneously with the CHEMVIEW-10™ and Roche's Chemstrip® urinalysis reagent test strips. Testing data for glucose and occult blood (Class II devices) was collected. A total of 188 specimens were tested. Glucose test results showed 99.5% agreement within the same color block and 100% agreement within one color block. Occult blood test results showed 86.7% agreement within the same color block and 97.34% agreement within one color block.

The CHEMVIEW-10™ is substantially equivalent to the Roche Chemstrip® in both test principle and clinical performance:

1. Both devices are visual qualitative and semi-quantitative test for the determination of urobilinogen, glucose, ketones, bilirubin, protein, nitrite, pH, blood, specific gravity and leukocytes in urine.

2. In a comparison study of 188 urine specimens for the two Class II analytes, the agreement between the CHEMVIEW™ and the Chemstrip® was demonstrated to be:

   a. 99.5% for glucose and
   b. 94.2 for occult blood.

3. Both products are similar in sensitivity:

	DETECTION RANGE	
ANALYTE	CHEMVIEW™	CHEMSTRIP®
UROBILINOGEN	1 to 12 mg/dl	1 to 12 mg/dl
GLUCOSE	100 to 1000 mg/dl	50 to 1000 mg/dl
KETONES	5 mg (+/-) to 80 mg/dl (+++)	+ (small) to +++ (large)
BILIRUBIN	0.5 mg/dl to 3 mg/dl	0.5 mg/dl
PROTEIN	30 to 1000 mg/dl	30 – 500 mg/dl
NITRITE	0.05 mg/dl	0.05 mg/dl
pH	5 to 9	5 to 9
OCCULT BLOOD	0.015 mg/dl 0r 10 RBC/µL	5 to 10 RBC/µL
SPECIFIC GRAVITY	1.000 to 1.030	1.000 to 1.030
LEUKOCYTES	Trace to +++	Trace to +++

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 7 2005

Ms. Nitza Katz
Vice President
Cenogenics Corporation
100 Route 520
Drawer 308
Morganville, NJ 07751

Re: k042641
Trade/Device Name: CHEMVIEW-10™
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: Class II
Product Code: JIL, KHE
Dated: December 21, 2004
Received: December 22, 2004

Dear Ms. Katz:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k042641

Device Name: CHEMVIEW

Indications For Use:

CHEMVIEW-10™ is a visual qualitative and semi-quantitative test for the determination of urobilinogen, glucose, ketones, bilirubin, protein, nitrite, pH, blood, specific gravity and leukocytes in urine. These metabolites are useful in the evaluation of renal, urinary and metabolic disorder.

The product will be marketed to physicians' office laboratories, clinics, hospitals and reference laboratories.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042641