Cenogenics Corporation

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K030533

APR 17 2003

Proprietary name: ACCUNATE™-ONE STEP
ACCUNATE™ONE STEP CASSETTE
ACCUNATE-CHOICE™
ACCUNATE™ HOME PREGNANCY TEST

Common name: Pregnancy test for urine or serum

Classification: 21CFR862.1155, Class II

Classification number: 75DHA

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

Contact: Nitza Katz
Vice President

ACCUNATE™ONE-STEP, ACCUNATE™ONE-STEP CASSETTE and ACCUNATE-CHOICE™ are rapid lateral flow colloidal gold immunological tests for the qualitative determination of human chorionic gonadotropin (hCG) in urine or in urine and serum for the early detection of pregnancy.

Comparison studies were conducted at three clinic sites. Urine specimens from patients seeking confirmation of pregnancy were tested simultaneously with ACCUNATE™ONE-STEP and ACCUNATE™ONE-STEP CASSETTE and the Abbott Test Pack Plus™. The Test Pack Plus™ is a similar colloidal gold test for the qualitative determination of hCG in urine for the early detection of pregnancy. A total of 131 specimens were tested. Test results showed 100% agreement with the Abbott Test Pack Plus™. TABLE 1A demonstrates distribution of positive and negative specimens.

TABLE 1A: Comparison of ACCUNATE™-ONE STEP and ACCUNATE™-ONE STEP CASSETTE with the Abbott Test Pack Plus™

	ACCUNATE™-ONE STEP	ACCUNATE™-ONE STEP CASSETTE	ABBOTT TEST PACK PLUS™
NO. OF POSITIVES	63	63	63
NO. OF NEGATIVES	68	68	68

Serum specimens from normal male and non pregnant females were tested simultaneously with ACCUNATE-CHOICE™ and Quidel's Quick-Vue®. The Quick-Vue is a similar device for the qualitative determination of hCG in urine or serum for the early detection of pregnancy. A total of 119 samples were tested. Test results showed 100% agreement with the Quick-Vue®. Table 1B shows the distribution of positive and negative samples.

TABLE 1B: Comparison of ACCUNATE-CHOICE™ with QUICK-VUE®.

	ACCUNATE-CHOICE™	QUICK-VUE®
NO. OF POSITIVES	59	59
NO. OF NEGATIVES	60	60

Twenty urine specimens and twenty serum specimens were spiked with hCG at concentrations of 5, 25, 50 and 100m IU/ml. Each urine specimen was tested at the hCG concentrations stated and at 0mIU/ml with ACCUNATE™ ONE-STEP, ACCUNATE™ ONE-STEP CASSETTES and ACCUNATE-CHOICE™. The serum specimens were tested with ACCUNATE-CHOICE™. Testing data demonstrates the sensitivity to be 25mIU/ml. Test results are shown in TABLE 2.

TABLE 2: Sensitivity Test Results

	hCG CONCENTRATION				
	0IU/ml	5mIU/ml	25mIU/ml	50mIU/ml	100mIU/ml
NO. OF SAMPLES TESTED	20	20	20	20	20
POSITIVE RESULTS	0	0	20	20	20
NEGATIVE RESULTS	20	20	0	0	0

A study comparing the test results obtained by the home user with the ACCUNATE™ HOME PREGNANCY TEST to the test results obtained by the professional user with the ACCUNATE™ ONE-STEP CASSETTE was performed at three clinic sites. A total of 107 participants were included in this study. The agreement between the home user and the laboratory professional test results was 98%. Table 3 shows the comparison test result data.

TABLE 3: Comparison of the test results reported by the Home User with the test results reported by the laboratory.

	Home User	Laboratory
Number of Positives	47	46
Number of Negatives	59	61
Number of Invalid	1	0
TOTAL	107	107

The above testing data demonstrates that ACCUNATE™-ONE STEP and the ACCUNATE™-ONE STEP CASSETTE are substantially equivalent to the Abbott Test Pack Plus™ and that the ACCUNATE-CHOICE™ is substantially equivalent to Quidel's Quick-Vue®. The test results obtained by the home user with the ACCUNATE™ HOME PREGNANCY TEST is substantially equivalent to the test results obtained by the laboratory professional with the ACCUNATE™ ONE-STEP CASSETTE. The devices are equivalent in test principle, sensitivity and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 7 2003

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

Re: k030533
Trade/Device Name: Accunate Home Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: February 10, 2003
Received: February 14, 2003

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030533

Device Name: ACCUNATE HOME PREGNANCY TEST

Indications For Use:

Accunate Home Pregnancy Test is an over-the-counter (OTC) one-step qualitative test for the detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030533

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

(Optional Format 1-2-96)