


Cenogenics Corporation

100 Route 520, Drawer 308, Morganville, New Jersey 07751 Telephone (732) 536-6457 / (800) 747-9457 / Fax (732) 972-8527

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Proprietary name: ACCUNATE™-ONE STEP
 ACCUNATE™ONE STEP CASSETTE

Common name: Pregnancy test for urine

Classification: 21CFR862.1155, Class II

Classification number: 75DHA JHI
UAC 8/25/99

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

Contact: Nitza Katz
 Vice President

ACCUNATE™-ONE STEP and ACCUNATE™-ONE STEP CASSETTE are rapid lateral flow colloidal gold immunological tests for the qualitative determination of human chorionic gonadotropin (hCG) in urine 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 1 demonstrates distribution of positive and negative specimens.

TABLE 1: 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

Twenty urine specimens from normal males and non pregnant females were spiked with hCG at concentrations of 5, 25, 50 and 100mIU/ml. Each urine specimen was tested at the hCG concentrations stated and at 0IU/ml with both the ACCUNATE™-ONE STEP and ACCUNATE™-ONE STEP CASSETTE. 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

The ACCUNATE™-ONE STEP and the ACCUNATE™-ONE STEP CASSETTE are substantially equivalent to the ABBOTT TEST PACK PLUS™ as demonstrated by the above testing data. The devices are equivalent in test principle, sensitivity and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 26 1999

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

Re: K992397
Trade Name: Accunate™-ONE STEP
Accunate™-ONE STEP CASSETTE
Regulatory Class: II
Product Code: JHI
Dated: July 15, 1999
Received: July 19, 1999

Dear Ms. Katz:

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

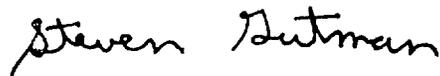
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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

CENOGENICS CORPORATION

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510(k) Number: K992397

Device Name: ACCUNATE™-ONE STEP

 ACCUNATE™-ONE STEP CASSETTE

Indications For Use:

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

The product will be marketed to physician's office laboratories, clinics and hospital and reference laboratories.

Jean Trevino for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 992397

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)