K023944

Summary of Safety and Effectiveness

FEB 11 2003

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person:	Thomas F. Flynn
Address:	Bayer Diagnostics 63 North Street Medfield, MA 02052
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e-mail:	thomas.flynn.b@bayer.com

2. **Device Information**

Proprietary Name:	Bayer Diagnostics Clinitest® hCG Pregnancy Test
Common Name:	An hCG test system is a device intended for early detection of Pregnancy. It is intended to measure hCG, a placental hormone in urine.
Classification Name:	Human Chorionic Gonadotropin (hCG) test system for the use in early detection of pregnancy.

3. **Predicate Device Information**

Name:	SureStep™ hCG/Combo (II) Pregnancy Test

4. **Device Description**

Human Chorionic Gonadotropin (hCG) test system for the use in early detection of pregnancy.

5. **Statement of Intended Use**

The Bayer Diagnostics Clinitest® hCG Pregnancy Test is an in vitro qualitative test for the rapid detection of human chorionic gonadotropin (hCG) at a cut-off concentration of 25 mIU/ml in urine. This test kit is used to obtain a visual result and is intended for professional and laboratory use.

6. **Summary of Technological Characteristics**

The Bayer Diagnostics Clinitest® hCG Pregnancy Test is a one-step chromatographic immunoassay for the rapid qualitative determination of human chorionic gonadotropin (hCG) in urine. The test cut-off is 25 mIU/ml hCG in urine. The test device contains a membrane strip that was pre-coated with anti-hCG capture antibody on the test line region and goat anti-mouse IgG on the control band region. During testing, the patient specimen is allowed to react with the colloidal gold particles that have been coated with anti-hCG monoclonal antibody. The mixture then moves along or across the membrane chromatographically by capillary action. For a positive result, a colored band with a specific anti-hCG-antibody-colloidal gold particle complex will form on the membrane in the test region. A strong colored line will always appear in the control region and another light colored line will always appear in the reference region. The color intensity of the reference line has been adjusted to a level of approximately 25 mIU/ml hCG. Comparison of the test line intensity to the reference line intensity will allow the estimation of whether the positive results are less than, equal to or greater than 25 mIU/ml hCG in serum.

7. **Performance Data**

Sensitivity

The Bayer Diagnostics Clinitest® hCG Pregnancy Test detects urinary hCG concentrations at 25 mIU/mL (Calibrated against WHO 3rd IRP).

A sensitivity study was performed by spiking negative urine, medium specific gravity with hCG standard to the concentrations of 0, 5, 10, 15, 20, 25 and 50 mIU/mL. The urine pool was prepared from 4 donors. The samples were blind-labeled and tested with the Clinitest® hCG Pregnancy Test using two different validation lots of product. A total of 280 samples were tested. Samples were randomly distributed among four visual readers for each product lot.

Clinitest hCG Lot 1 N=140

hCG Concentration mIU/mL	0	5	10	15	20	25	50
N =	20	20	20	20	20	20	20
Number of Positives	0	5	9	13	15	18	20
Number of Negatives	20	15	11	7	5	2	0

Clinitest hCG Lot 2 N=140

hCG Concentration mIU/mL	0	5	10	15	20	25	50
N =	20	20	20	20	20	20	20
Number of Positives	0	3	9	10	13	19	20
Number of Negatives	20	17	11	10	7	1	0

Accuracy

Two external sites were contracted to perform testing on the Clinitest® hCG test (validation lot 59421). A total of 200 visual test results were obtained. Site one tested 98 samples and site 2 tested 102 samples. The samples were prepared by pooling four urine specimens of medium specific gravity, aliquoting and spiking with hCG. The samples were divided by site.

Clinitest® hCG Visual Results

Urine Samples for External Study			
Sample	Site 1	Site 2	Total
0 mIU/mL Lablot # 1	33	35	68
25 mIU/mL Lablot # 2	33	33	66
100 mIU/mL Lablot # 3	32	34	66
			200

The results of the Clinitest® hCG external site data compared to a commercial hCG assay results The commercial assay was an immunoradiometric assay (Magnetic Solid Phase) made by ADALTIS Italia, purchased through Polymedco, Inc. There was 100% agreement of sample results with the commercial hCG assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 11 2003

Mr. Thomas F. Flynn
Director of Regulatory Affairs
Bayer Diagnostics
Bayer Corporation
63 North Street
Medfield, MA 02052-1688

Re: k023944
Trade/Device Name: Bayer Diagnostics Clinitest® hCG Pregancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: November 21, 2002
Received: November 26, 2002

Dear Mr. Flynn:

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). 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/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): K023944

Device Name: Bayer Diagnostics Clinitest® hCG Pregnancy Test

Indications for Use:

The Bayer Diagnostics Clinitest® hCG Pregnancy Test is an in vitro qualitative test for the rapid detection of human chorionic gonadotropin (hCG) at a cut-off concentration of 25 mIU/ml in urine. This test kit is used to obtain a visual result and is intended for professional and laboratory use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023944

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)