K032563

DEC 2 3 2003

Appendix A
Summary of Safety and Effectiveness

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

1. **Submitters Information**

Contact person:	Mary E. Gray, RAC NPT Regulatory Affairs Manager
Address:	Bayer Healthcare, LLC Subsidiary of Bayer Corporation 63 North Street Medfield, MA 02052
Phone:	(508) 359-3826
Fax:	(508) 359-3776 or (508) 359-3356
e-mail address:	mary.gray.b@bayer.com

Date Summary Prepared: November 7, 2003

2. **Device Information**

Proprietary Name:	Clinitest® hCG Pregnancy Test
Common Name:	hCG Test System
Classification Name:	Radioimmunoassay, Human Chorionic Gonadotropin
Classification Number:	21 CFR 862.1155, Class II
Classification Panel:	Clinical Chemistry and Clinical Toxicology

3. **Predicate Device Information**

Device Name:	Clinitest hCG Pregnancy Test	Quidel QuickVue One-Step hCG Combo
Manufacturer:	Bayer Healthcare, LLC	Quidel Corporation
510(k) Number:	# K023944	# K020801

Appendix A
Summary of Safety and Effectiveness

4. **Device Description**

   The Clinitest® hCG is a qualitative test for the rapid detection of human chorionic gonadotropin (hCG) in urine. The device is read by the Clinitek Status instrument.

5. **Statement of Intended Use**

   The Bayer Healthcare Clinitest hCG Pregnancy Test is for in vitro diagnostic use as a qualitative method in the rapid detection of human chorionic gonadotropin (hCG) in urine specimens. The test is utilized with the Clinitest Status analyzer and is intended for near patient (point of care) and centralized laboratory locations.

6. **Summary of Technological Characteristics**

   The Clinitest hCG Pregnancy Test is similar in technological characteristics, device performance and intended use, therefore, is substantially equivalent to the predicate devices, the Clinitest hCG Pregnancy Test (**# K023944**) and the Quidel QuickVue One-Step hCG Combo test (**# K020801**).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 3 2003

Ms. Mary E. Gray
NPT Regulatory Affairs Manager
Bayer Healthcare, LLC
Subsidiary of Bayer Corporation
63 North Street
Medfield, MA 02052

Re: k032563
Trade/Device Name: Clinitest® hCG Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: November 7, 2003
Received: November 10, 2003

Dear Ms. Gray:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032563

Device Name: Bayer Healthcare Clinitest® hCG Pregnancy Test

Indications for Use:

The Bayer Healthcare Clinitest hCG Pregnancy Test is for in vitro diagnostic use as a qualitative method in the rapid detection of human chorionic gonadotropin (hCG) in urine specimens. This test is used to obtain a Clinitek Status analyzer result of positive, borderline or negative and is intended for near patient (point-of-care) and centralized laboratory locations.

(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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032563