

**510(k) SUMMARY**

JAN 16 2003

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for the Contrast® II hCG Urine/Serum test.

1. Sponsor/Applicant Name and Address:

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

2. Sponsor Contact Information:

E.V. Goorchenko  
Associate Director, Regulatory Affairs  
Phone: 858/777-2614  
FAX: 858/452-3258  
Email: Gene.Goorchenko@genzyme.com

3. Date of Preparation of 510(k) Summary:

October 21, 2002

4. Device Trade or Proprietary Name:

Contrast® II hCG Urine/Serum Test

5. Device Common/Usual or Classification Name:

hCG Test System

6. Legally Marketed Devices to which Equivalence is Being Claimed:

Quidel QuickVue® One-Step hCG Combo Test (K 020801)

7. Device Description

Intended Use

The Genzyme Diagnostics Contrast® II hCG Urine/Serum test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum for the early detection of pregnancy. This test is for use in physicians' offices and clinical laboratories.

Principle of the Device

The Contrast® II Urine/Serum device is a solid phase, sandwich-format immunochromatographic assay for the qualitative detection of hCG. Urine or serum is added to the sample well of the test device using the fixed volume AccuPipette® provided. The sample migrates through reaction pads where hCG, if present in the sample, binds to a monoclonal anti-hCG dye conjugate. The sample then migrates across a membrane towards the results window, where the labeled monoclonal antibody-hCG complex is captured at a test line region containing immobilized monoclonal anti- $\alpha$  hCG. Excess conjugate will flow past the test line region and be captured at a control line region containing an immobilized antibody directed against the anti-hCG dye conjugate (with or without hCG complexed to it).

The appearance of two gray or black bands in the results window indicates the presence of hCG in the sample. If a detectable level of the hCG is not present, only the control band will appear in the results window.

8. Comparison of Technological Characteristics of Genzyme Contrast® II hCG Urine/Serum Test with Legally Marketed Device:

The similarities with, and differences between, the Contrast® II hCG Urine/Serum test and the Quidel One-Step device are described in Table 1.

9. Agreement with Predicate Device:

A total of 201 urine samples and 319 serum samples were tested and compared to the results obtained with a currently marketed qualitative hCG assay. When tested according to the instructions and limits in the package inserts, the results obtained with the different assays were in agreement with the exception of two discrepant samples. One urine sample and one serum sample produced positive responses with the Quidel QuickVue® One-Step Combo hCG test while the Contrast® II Urine/Serum test produced negative results for those samples. The discrepant samples were tested

with a quantitative assay (Diagnostics Products Coat-A-Count® hCG IRMA) and found to contain 2.6 mIU hCG/mL in the urine sample and 0 mIU hCG/mL in the serum sample.

**Table 1. Summary of Device Similarities and Differences**

	<b>Genzyme Contrast® II hCG Urine/Serum Test</b>	<b>Quidel QuickVue® hCG-Combo Test</b>
Assay Format	Lateral flow immunoassay	Lateral flow immunoassay
Result Format	Visible lines: Negative=one gray or black Control Line Positive=one gray or black Control Line and one gray or black Test Line	Visible lines: Negative =blue procedural Control Line Positive = one pink-to-purple Test Line and one blue Control Line
Specimen	Urine or Serum	Urine or Serum
Antibodies	Mouse monoclonal and goat polyclonal	Mouse monoclonal and goat polyclonal
Internal Control	Yes	Yes
Time To Result	Urine: Read result at 3 minutes Serum: Read result at 5 or 7 minutes	Urine: Read result at 3 minutes Serum: Read result at 5 minutes
Analytical Sensitivity	Urine: 20 mIU/mL Serum: 10 mIU/mL	Urine: 20 mIU/mL Serum: 10 mIU/mL



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 16 2003

Mr. E. V. Goorchenko  
Associate Director, Regulatory Affairs  
Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

Re: k023544  
Trade/Device Name: Contrast<sup>®</sup> II hCG Urine/Serum Test  
Regulation Number: 21 CFR 862.1155  
Regulation Name: Human chorionic gonadotropin (HCG) test system  
Regulatory Class: Class II  
Product Code: JHI  
Dated: October 21, 2002  
Received: October 22, 2002

Dear Mr. Goorchenko:

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.

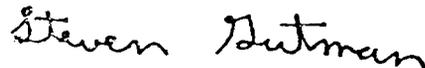
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 –

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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: New Application **K023544**

**Device Name:**

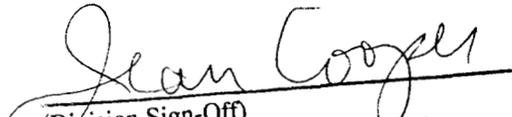
Contrast® II hCG Urine/Serum Test

**Indications for Use:**

The Contrast® II hCG Urine/Serum Test system is intended for the qualitative detection of human chorionic gonadotropin (hCG), a placental hormone, in urine or serum for the early detection of pregnancy. The test is intended for use by health care professionals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number **K023544**

  
Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use  
(Optional Format 1-2-96)