DEC 19 1997

K974052

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Product:
QuickVue® Semi-Q hCG-Combo

Manufacturer:
QUIDEL Corporation
10165 McKellar Court
San Diego, CA 92121
U.S.A.

Device Classification:
The device, QuickVue Semi-Q hCG-Combo, is similar to other FDA-cleared devices used for the detection of human chorionic gonadotropin (hCG) in serum or urine. The test is used in the early detection of pregnancy and is intended to measure hCG, a placental hormone, in serum, plasma or urine (21 CFR 862.1155). The FDA has proposed that hCG test systems be classified as Class II.

Intended Use:
The test is a rapid immunoassay for the semi-quantitative detection of hCG in serum and the qualitative detection of hCG in urine. This test is to be used for the early detection of pregnancy.

Physiologic Basis for the Assay:
Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the trophoblastic cells of the developing placenta as early as 7 to 8 days after ovulation. This hormone stimulates the production of progesterone and estradiol which are required to sustain pregnancy. In normal pregnancy, serum levels of hCG continue to rise during the first trimester to levels as high as 100,000 mIU/mL. Serum hCG is rapidly cleared in the urine and the concentration of hCG in serum is approximately equal to the concentration in urine. HCG is an excellent indicator of pregnancy early in the gestational period.

Principle of the Test:

Serum or urine is added to the Sample Well on the Test Cassette. Shortly after addition of the sample, a blue procedural Control Line will appear in the Result Window. If hCG is present in the sample, a pink-to-purple Test Line will also appear. If hCG is not present, only the blue procedural Control Line will appear.

Serum results are interpreted by comparing the color development of the Test Line with a Reference Line. Serum results are reported as negative, positive less than 25 mIU/ml or positive greater than 25 mIU/mL. Urine results are interpreted as negative or positive.

Safety and Effectiveness:

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to other commercially available products for the detection of hCG in serum or urine. These studies included the following:

- The test was shown to be similar to other commercially distributed *in vitro* tests in terms of features and intended use.
- The test was shown to have excellent intra- and inter-assay precision.
- Lot-to-lot consistency analyses showed the test to be reproducibly manufacturable.
- Common drugs, chemicals, and biologicals were shown not to interfere with the test's performance.
- Using serum and urine samples obtained from women presenting for pregnancy testing, a direct comparison of the test to the Hybritech® ICON® II HCG ImmunoConcentration™ Assay for hCG detection was conducted. An accuracy exceeding 99% was observed.
- Physician's Office Laboratory studies were conducted to show that doctor's office personnel with diverse educational backgrounds and work experience could perform the test accurately and reproducibly. Testing was performed at three geographically distinct sites in the United States. The results obtained at each site agreed 100% with the expected results.

Conclusion:

These studies demonstrated the substantial equivalence of the QuickVue Semi-Q hCG-Combo to existing products already marketed. They further demonstrated the suitability of the product for use by health care professionals. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 19 1997

Robin Weiner
Vice President, Clinical Develop. & Reg. Affairs
QUIDEL Corporation
10165 Mc Kellar Court
San Diego, California 92121

Re: K974052
QuickVue® Semi-Q hCG-Combo
Regulatory Class: II
Product Code: JHI
Dated: October 24, 1997
Received: October 27, 1997

Dear Ms. Weiner:

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 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 have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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/dsmamain.html".

Sincerely yours,

Steven Gutman

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

510(k) Number (if known): _____

Device Name: **QuickVue® Semi-Q hCG-Combo**

Indications for Use:

The QuickVue® Semi-Q hCG-Combo is a one-step immunoassay intended for the semi-quantitative detection of human chorionic gonadotropin (hCG) in serum and the qualitative detection of hCG in urine for the early detection of pregnancy. The QuickVue Semi-Q hCG-Combo is intended for use by health care professionals.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974052

(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)

Quidel Corporation
10165 McKellar Court ▪ San Diego, CA 92121