JAN 26 1998

K974821

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

Product

Bluetest® Pregnancy Test; or
RapidVue® Pregnancy Test

Manufacturer

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

Device Classification

The device, Bluetest Pregnancy Test, also sold under the brandname RapidVue Pregnancy Test, is similar to other FDA-cleared devices used for the qualitative detection of human chorionic gonadotropin (hCG). The test is used in the early detection of pregnancy and is intended to measure hCG, a placental hormone, in 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 qualitative detection of hCG in urine as an aid in the early detection of pregnancy. The test is intended for over-the-counter home use.

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

The test, a sandwich-format, lateral-flow immunoassay, employs monoclonal and polyclonal antibodies. If the sample contains hCG, a pink and blue plus sign (+) is visible in the large Result Window, along with a blue line in the small Control Window to indicate a positive result. If hCG is not present in the sample, a blue minus sign (–) is visible in the large Result Window, along with a blue line in the small Control Window, to indicate a negative result.

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 qualitative detection of hCG. These studies included the following:

- The test was shown to be similar to other commercially distributed 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 urine samples obtained from women presenting for pregnancy testing, a direct comparison of the test was conducted in a multi-center clinical study.
- A consumer study was conducted in order to show that lay users could read the package insert, perform the test in their home and obtain results similar to results obtained by clinic personnel.

Conclusion

These studies demonstrated the substantial equivalence of the test to existing products already marketed. They further demonstrated the suitability of the product for over-the-counter home use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 26 1998

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

Re: K974821
Bluetest® Pregnancy Test; or RapidVue® Pregnancy Test
Regulatory Class: II
Product Code: LCX
Dated: December 22, 1997
Received: December 23, 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: Bluetest® Pregnancy Test; or RapidVue® Pregnancy Test

Indications for Use:

The Bluetest® Pregnancy Test, also sold under the brandname RapidVue® Pregnancy Test, is a one-step immunoassay intended for the qualitative detection of hCG in urine for the early detection of pregnancy. The test is intended for over-the-counter home use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Montgomery

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number 974821

Prescription Use_____ OR Over-The Counter Use ✓

(Per 21 CFR 801.109)

(Optional Format 1-2-96)