MAY 17 2002

K020801

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

Product:
QuickVue® One-Step hCG-Combo

Manufacturer:
Quidel Corporation
10165 McKellar Court
San Diego, California 92121
U.S.A.

Device Classification:
The device, QuickVue One-Step hCG-Combo, is similar to other FDA-cleared devices used for the qualitative 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 qualitative detection of hCG in serum or 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-red Test Line will also appear. If hCG is not present, only the blue procedural Control Line will appear.

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 in serum or urine. These studies included the following:

1. The test was shown to be similar to other commercially distributed *in vitro* tests in terms of features and intended use.

2. The test was shown to have excellent intra- and inter-assay precision.

3. Lot-to-lot consistency analyses showed the test to be reproducibly manufacturable.

4. Common drugs, chemicals, and biologicals were shown not to interfere with the test's performance.

5. Using samples obtained from women presenting for pregnancy testing, a direct comparison of the test to to a commercially available qualitative hCG test was conducted. An accuracy exceeding 99% was observed.

6. Physicians' Office studies were conducted to demonstrate that physician office personnel with diverse educational backgrounds and work experience could perform the test accurately and reproducibly.

Conclusion:
These studies demonstrated the substantial equivalence of the QuickVue One-Step hCG-Combo test to currently marketed devices which have been reviewed and cleared through the 510(k) notification process. 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 17 2002

Ms. Jennifer S. Hankard
Regulatory Affairs Manager
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Re: k020801
Trade/Device Name: QuickVue® One-Step hCG-Combo
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: March 11, 2002
Received: March 12, 2002

Dear Ms. Hankard:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 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,

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

XIII. INDICATIONS FOR USE (Separate Page):

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510(k) Number (if known): K020801

Device Name: **QuickVue® One-Step hCG-Combo**

Indications for Use:

The QuickVue One-Step hCG-Combo is a one-step immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum or urine for the early detection of pregnancy. The test is intended for use by health care professionals.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020801

(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)