K102175

AUG 25 2010

510(k) SUMMARY

Submitted By:	Quidel Corporation 10165 McKellar Court San Diego, California 92121 Telephone: 858-552-1100 x1015 Fax: 858-646-8045
Submission Contact:	Michelle Bodien
Date Prepared:	August 23, 2010
Device Trade Name:	RapidVue® hCG Test
Common Name:	hCG pregnancy test
Predicate Device:	QuickVue One-Step hCG Urine Test (K020799)
Product Code	JHI
Device Classification/Name:	21 CFR 862.1155 / Human chorionic gonadotropin (hCG) Test System The RapidVue hCG test is similar to other FDA-cleared devices used for the qualitative detection of human chorionic gonadotropin (HCG) for the early detection of pregnancy. The Food and Drug Administration has classified test systems for the detection of pregnancy as Class II.
Intended Use:	The RapidVue hCG test is an immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for use by health care professionals
Physiologic Basis of the Test:	Human chorionic gonadotropin is a hormone produced by the placenta shortly after implantation. Since hCG is present in the urine of pregnant women, it is an excellent marker for confirming pregnancy.

Device Description:

The RapidVue hCG test uses a monoclonal antibody specific to the beta subunit of hCG in a single-step technology to accurately detect hCG.

The Dipstick is dipped in urine. If hCG is present in the specimen at a level of 25 mIU/mL or greater, a pink-to-red Test (T) Line will appear along with a blue procedural Control (C) Line in the test result area. If hCG is present at lower levels, or not present in the specimen, only a blue procedural Control Line will appear in the test result area.

Device Comparison:

Features	RapidVue hCG (Proposed)	QuickVue One-Step hCG Urine (K020799)
Intended Use	The RapidVue hCG test is an immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for use by health care professionals	The QuickVue One-Step hCG-Urine test is a one-step immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for use by health care professionals.
Analyte	Human Chorionic Gonadotropin	Human Chorionic Gonadotropin
Specimen Type	Urine	Urine
Format	Lateral-flow immunoassay (Dipstick)	Lateral-flow immunoassay (Cassette)
Total steps	1	1
Read Time	3 minutes	3 minutes
Sensitivity	25 mIU/mL	25 mIU/mL
Test Interpretation	Blue procedural control line Pink-to-red test line	Blue procedural control line Pink-to-red test line
Test strip components	Test Line* Polyclonal goat anti-alpha hCG antibody is immobilized in the test zone on the nitrocellulose membrane Indicator* Monoclonal anti-hCG antibody coupled to red-colored beads is incorporated into the Label Pad. Control Line* An unrelated protein capable of binding the blue latex is spotted in the control zone on the nitrocellulose membrane.	Test Line Polyclonal goat anti-alpha hCG antibody is immobilized in the test zone on the nitrocellulose membrane Indicator Monoclonal antibody specific to the beta subunit of hCG is incorporated into the Label Pad. Control Line An unrelated protein capable of binding the blue latex is spotted in the control zone on the nitrocellulose membrane.

*Note: The monoclonal antibodies used for the Test Line and the Indicator in the RapidVue hCG test are identical to those used in the predicate QuickVue One-Step hCG Urine test. The components that generate the Control Line are also identical.

Summary of Performance Data:

Numerous analytical studies were undertaken to document the performance characteristics and the substantial equivalence of the RapidVue hCG test to the predicate device. These studies included the following:

1. Assay Sensitivity: to verify that the sensitivity of the RapidVue hCG test is consistent with QuickVue One-Step hCG Urine test.
2. Prozone Effect: to verify that no prozone effect is observed with the RapidVue hCG test as is consistent with QuickVue One-Step hCG Urine test.
3. Urinary pH: to verify that the RapidVue hCG test is not affected by variations in urinary pH.
4. Procedural Flex Testing: to demonstrate the robustness of the RapidVue hCG test and its test procedure.
5. Clinical Sample Testing: to verify that the accuracy of the RapidVue hCG test is consistent with QuickVue One-Step hCG Urine test using procured clinical urine samples.
6. Physician Office Laboratory (POL) Reproducibility Study: to evaluate the performance of the RapidVue hCG test by physician office personnel.

Conclusion:

The results of these studies demonstrate that the RapidVue hCG test is substantially equivalent with the predicate QuickVue One-Step hCG Urine test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AUG 25 2010

Quidel Corporation
c/o Ms. Michelle Bodien
Senior Regulatory Affairs Specialist
10165 McKellar Court
San Diego, CA 92121

Re: k102175
Trade Name: RapidVue hCG test
Regulation Number: 21 CFR §862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system.
Regulatory Class: Class II
Product Codes: JHI
Dated: July 30, 2010
Received: August 2, 2010

Dear Ms. Bodien:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K102175

510(k) Number (if known): K102175

Device Name: RapidVue hCG test

Indications For Use:

The RapidVue hCG test is an immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy. The test is intended for use by health care professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K102175