K020578

JUN 21 2002

510(k) Summary
QuPID® Plus E.R.

QuPID® Plus E.R. pregnancy device is intended for qualitative determination of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. The test is comprised of colored dye coated with polyclonal antibodies specific for hCG, immobilized antibodies against hCG and monoclonal anti-mouse IgG antibodies. The assay is conducted by adding specimen, urine or serum, to the test device and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody hCG colored conjugate and form a colored line in the Specimen Area of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line in the Control Area will always appear regardless of the presence or absence of hCG.

Classification Name: Gonadotropin
Classification Number: 75DHA, Class II

Predicate Device: Abbott Test Pack® Plus

PERFORMANCE CHARACTERISTICS

Accuracy:

An evaluation was conducted comparing the results obtained using QuPID® Plus E.R. and another commercially available urine/serum membrane test. The study included 300 urine and 72 serum specimens tested with both assays. The following results were found:

	Positive Urine Results	Negative Urine Results
QuPID® Plus E.R.	150	150
Commercially Available Test	150	150

	Positive Serum Results	Negative Serum Results
QuPID® Plus E.R.	21	51
Commercially Available Test	21	51

QuPID® Plus E.R. showed a 100% concordance with the other commercially available test for accuracy.

Specificity:

The addition of hLH (500 mIU/ml), hFSH (1000 mIU/ml), and hTSH (1000 µIU/mL) to positive and negative urine/serum specimens showed no cross-reactivity.

Standardization:

The test has been standardized to the World Health Organization Third International Standard.

Sensitivity:

QuPID® Plus E.R. detects hCG concentration of 10 mIU/mL or greater in serum and 20 mIU/mL in urine.

CLINICAL STUDIES

Clinical Studies were conducted at three locations. The tests were conducted by individuals of diverse educational backgrounds and work experience. The results of these studies showed a 100% concordance with other commercially available tests.

CONCLUSION

The QuPID® Plus E.R. is substantially equivalent in principle and performance to Abbott's Test Pack® Plus as shown in this summary.

Summary prepared by Kirk Johnson, QA/QC Manager on January 30, 2002

Stanbio Laboratory
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Boerne, Texas 78006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kirk Johnson
QA/QC Manager
Stanbio Laboratory
1261 North Main Street
Boerne, TX 78006

JUN 21 2002

Re: k020378
Trade/Device Name: QuPID Plus E.R.
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: April 25, 2002
Received: April 26, 2002

Dear Mr. Johnson:

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

510(k) Number (if known): K020378

Device Name: QuPID Plus E.R.

Indications For Use:

QuPID Plus E.R. is for the qualitative determination of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020378

(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)