K023027

DEC 16 2002

510(k) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

YD Diagnostics
228-8Chamsil-Dong,Songapa-Gu
Keuk-Dong A,Bldg.2F
Seoul,138-220,Korea

Contact Person: **Mr. J.M. Lee**
Contact Phone Number: **82-2-2233-5687**
1-800-365-6146

Date of Summary: June 1,2002

Trade Name: Preg-Q Early Pregnancy Test

Classification Name: Radioimmunoassay,Human Chorionic Gonadotropin

Predicate Device: Testpack Plus HCG Urine K954029

Intended Use: The Preg-Q early pregnancy test is a rapid visual test for the qualitative detection of hCG in urine to aid in the determination of pregnancy. This test is for over-the - counter, central laboratory, and point of care hospital use..

Device Comparison:

	Preg-Q Early Pregnancy Test	Testpack Plus HCG Urine
510(k)		K954029
Testing Completed	Interference	Same
	Accuracy	Same
	Sensitivity	Same
	Specificity	Same
	Reading Time	Same
	OTC Comparison	N/A
Intended Use	Detection of hCG	Same
Intended Specimen	Urine	Same
Results	Qualitative	Qualitative
Test Time	5 minutes	5 minutes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

YD Diagnostics
c/o Mr. Arthur J. Ward
RMS Regulatory and Marketing Services, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

DEC 16 2002

Re: k023027
Trade/Device Name: Preg-Q Early Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: October 28, 2002
Received: October 29, 2002

Dear Mr. Ward:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023027

Device Name: Preg-Q Early Pregnancy Test

Indications For Use:

The Preg-Q hCG Early Pregnancy Test is a rapid visual test for the qualitative detection of hCG in urine to aid in the determination of pregnancy. This test is for over- the-counter, central laboratory, and point of care hospital use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023027

Prescription Use ✓ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)