

OCT 31 1997

K973570

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: QuickCard HCG One Step Pregnancy Test (9011)

Description: Immunoassay for the Qualitative Detection of Human Chorionic Gonadotropin (hCG) in Urine for the Detection of Early Pregnancy

Name of Manufacturer: Phamatech
9265 Activity Road #112
San Diego, California, 92126, USA

Intended Use: The QuickCard HCG One Step Pregnancy Test is intended to detect the presence of Human Chorionic Gonadotropin (hCG) in Urine for the women who suspect they may be pregnant. HCG is a well know and established analyte used to confirm pregnancy because of its early appearance in urine following conception followed by a dramatic increase in concentration.

Technology: The QuickCard HCG One Step Pregnancy Test, like many commercially available pregnancy test kits, qualitatively measures the presence of HCG by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Unipath Clearview HCG (Mountainview, CA 94043), Abbot Laboratories' Fact Plus (Abbot Park, IL 60064) and the Syntron Bioresearch Be Sure Pregnancy Test (Carlsbad, CA 92008). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / HCG / antibody complexes.

Performance: The product performance characteristics of the QuickCard HCG One Step Pregnancy Test were evaluated in a clinical sample correlation study and a blind labeled spiked HCG study. The results of these studies demonstrate the Phamatech QuickCard HCG One Step Pregnancy Test to be substantially equivalent to the reported performance characteristics of other commercially available test for the qualitative detection of early pregnancy. Correlation studies, using clinical specimens, produced a >99% correlation when compared to the Quidel RapidVue (San Diego, CA 92121) and the Syntron Bioresearch Be Sure Pregnancy Test (Carlsbad, CA 92008). A blind labeled spiked consumer study was performed; the Phamatech QuickCard exhibited excellent sensitivity (122/123), specificity (122/123), and accuracy (244/246) in the hands of lay users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickCard HCG One Step Pregnancy Test is substantially equivalent to a variety of pregnancy tests currently in commercial distribution.

IV. Consumer Survey:

Introduction:

- A study was conducted at five geographically distinct locations using a panel of coded specimens to demonstrate that lay people, not clinical professionals, could perform the QuickCard HCG One Step Pregnancy Test reproducibly and obtain accurate results. The proficiency panel contained negative (0 mIU/mL) and low positive (40 mIU/mL) hCG urine specimens.
- Individuals were instructed to follow the QuickCard HCG One Step Pregnancy Test package insert to perform and read the assay. In no case was there any verbal communication between the trial participant and Phamatech with regard to assay procedure or interpretation. Trial participants were supplied with coded specimens and QuickCard HCG One Step Pregnancy Tests. Most participants received a set containing 1 coded positive sample and 1 coded negative sample. One participant received 2 coded negative samples.

Study Population:

- Trial participants ranged in age from 16 to 55 years of age. Respondents were of diverse occupational backgrounds, from students and housewives to accountants, chemists and pharmacists. Approximately 25% of the respondents were of Asian decent, 10% were Hispanic, while the remainder were African American and Caucasian.

Study Design:

- Coded urine samples were prepared as follows:
 - Samples 1 and 3 were normal pooled male urine samples spiked to 40 mIU/mL hCG (WHO 1st IRP).
 - Samples 2 and 4 were 0 mIU/mL hCG.
- Trial participants each were sent two (2) QuickCard HCG One Step Pregnancy Tests, two (2) coded samples, 1 pair of latex gloves and general instructions (see page 39). Included in each "kit" was a survey explanation, a questionnaire (see page 40) and a self-addressed, stamped envelope.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 31 1997

Tuan Pham
President
Phamatech, Inc.
9265 Activity Road, # 112/113
San Diego, California 92126

Re: K973570
Quick Card HCG One Step Pregnancy Test
Regulatory Class: II
Product Code: LCX
Dated: August 17, 1997
Received: September 19, 1997

Dear Mr. Pham:

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 (Pre-market 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 pre-market 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.

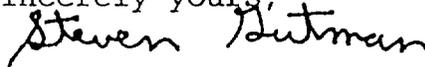
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Phamatech

510(k) Number (if known):

Device Name: QuickCard HCG One Step Pregnancy Test

Indications for Use:

An hCG pregnancy test intended for over the counter use by lay persons is an in vitro diagnostic test for the qualitative identification of human Chorionic Gonadotropin (hCG), a human hormone, in urine. Measurements that are obtained by this device are used in the diagnosis of pregnancy.

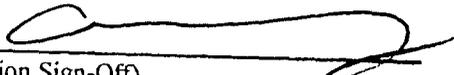
PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH Office of Device Evaluation (ODE)

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

Prescription Use: _____ OR Over the Counter:

Per 21 CFR 801.109


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number 12973570