APR 16 1998

K980736

ATTACHMENT A

Revised 510(k) Summary

ACON hCG Urine/Serum One Step Pregnancy Test Strip

10. 510(k) Summary

A. Name and Address of Submitter

Acon Laboratories, Inc.
115 Research Drive
Bethlehem, PA 18015
Telephone: 609-397-8511
FAX: 609-397-8224
Contact Person: Patricia E. Bonness, Official Correspondent
Date 510(k) Summary was prepared: April 3, 1998

B. Device Names

Proprietary Name: ACON® hCG Urine/Serum One Step Pregnancy Test

Common Name: Pregnancy Test

Classification Name: Human Chorionic Gonadotropin (hCG) Test System

C. Legally Marketed Device

The ACON® hCG Urine/Serum One Step Pregnancy Test has been determined to be substantially equivalent to the TestPack®Plus™ hCG Combo pregnancy test (K903219) currently in commercial distribution by Abbott.

D. Device Description

The ACON hCG Urine/Serum One Step Pregnancy Test is a rapid chromatographic immunoassay (membrane particle assay).

E. Intended Use

The ACON hCG Urine/Serum One Step Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin in urine or serum.

F. Comparison with Predicate Device

A summary comparison of the features of the ACON hCG and the TestPack®Plus™ hCG Combo pregnancy tests is provided in Table 1 on the following page.

Table 1

Feature Comparison of the ACON hCG and TestPack®Plus™ hCG Pregnancy Tests

Parameter	ACON hCG	TestPack®Plus™ hCG
Intended Use	qualitative detection of hCG in urine and serum	qualitative detection of hCG in urine and serum
Indication for Use	early detection of pregnancy	early detection of pregnancy
Specimen	urine and serum	urine and serum
Endpoint	colored lines	colored lines, plus & minus
Format	test strips	test strips within a device
Methodology	membrane particle assay	membrane particle assay
Storage	15° to 30° C	15° to 30° C
Test Time	3 to 5 minutes	3 to 5 minutes
Sensitivity	25 mIU/ml	20 mIU/ml
Accuracy	≥99%	≥99%
Specificity	No interferences	No interferences
Standardization	WHO Third International Standard	WHO Third International Standard

G. Performance Data

Accuracy

A multi-center clinical evaluation was conducted which compared the results obtained in tests of 155 urine specimens using the ACON hCG Urine/Serum One Step Pregnancy Test and another commercially available membrane particle assay . The results of this study showed that both tests identified the same 76 negative and 79 positive results. The serum study included 57 specimens and both assays identified 38 negative and 19 positive results. The results of both urine and serum studies demonstrate a 100% overall agreement (for an Accuracy of ≥99%) of the ACON hCG Urine/Serum One Step Pregnancy Test in comparison to the other serum/urine test.

Sensitivity

Sensitivity was determined by spiking 20 clinical samples from normal, nonpregnant females with five different concentrations of hCG (0, 15, 20, 50, 100 mIU/ml). The detection limit claimed for the ACON hCG pregnancy test is 25 mIU/ml. All samples tested at concentrations of hCG as low as 15 mIU/ml produced positive results.

Specificity

Specificity studies were performed on specimens with high physiological concentrations of luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulating hormone (TSH). Negative results were obtained with all specimens tested with 300 mIU/ml hLH, 1000 mIU/ml hFSH, and 1000μIU/ml hTSH.

Interfering Substances

No interference was observed in studies of specimens containing the following substances:

Acetaminophen	20	mg/dl
Acetylsalicylic acid	20	mg/dl
Ascorbic acid	20	mg/dl
Atropine	20	mg/dl
Caffeine	20	mg/dl
Gentisic acid	20	mg/dl
Glucose	2	g/dl
Hemoglobin	1	mg/dl

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 16 1998

Patricia E. Bonness
Official Correspondent
Acon Laboratories, Inc.
115 Research Drive
Bethlehem, Pennsylvania 18015

Re: K980736
ACON™ hCG Urine/Serum One Step Pregnancy Test
Regulatory Class: II
Product Code: JHI
Dated: February 23, 1998
Received: February 25, 1998

Dear Ms. Bonness:

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 (Premarket 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 premarket 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.

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 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): K980736

Device Name: ACON™hCG Urine/Serum One Step Pregnancy Test

Indications For Use:

The ACON hCG Urine/Serum One Step Pregnancy Test is a rapid qualitative chromatographic immunoassay for the detection of human chorionic gonadotropin in urine or serum.

The ACON hCG Urine/Serum One Step Pregnancy Test is indicated for use as an aid in the early detection of pregnancy. This device is intended to be used in the clinical laboratory and/or physician's office.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980736