

NOV 18 1998

10. 510(k) Summary

A. Name and Address of Submitter

**Acon Laboratories, Inc.
3140-B Tilghman Street, Suite 215
Allentown, PA 18104**

**Telephone: 609-397-8511
FAX: 609-397-8224**

Contact Person: Patricia E. Bonness, Official Correspondent

Date 510(k) Summary was prepared: November 11, 1998

B. Device Names

Proprietary Name: ACON™ Midstream Pregnancy Test

Common Name: Pregnancy Test

Classification Name: Human Chorionic Gonadotropin (hCG) Test System

C. Legally Marketed Device

The ACON™ Midstream Pregnancy Test has been determined to be substantially equivalent to the SAS Pregnancy Test (K926204) currently in commercial distribution by SA Scientific, San Antonio, TX.

D. Device Description

The ACON Midstream Pregnancy Test is a rapid chromatographic immunoassay (membrane particle assay).

E. Intended Use

The ACON Midstream Pregnancy Test is intended for home use, in the qualitative detection of human chorionic gonadotropin in urine.

F. Comparison with Predicate Device

A summary comparison of the features of the ACON Midstream and the SAS One-Step Pregnancy Tests is provided in Table 1 on the following page.

Table 1

Feature Comparison of the ACON Midstream and SAS One-Step Pregnancy Tests

<u>Parameter</u>	<u>ACON Midstream</u>	<u>SAS One-Step</u>
Intended Use	qualitative detection of hCG in urine and serum home use (OTC)	qualitative detection of hCG in urine and serum professional use
Indication for Use	early detection of pregnancy	early detection of pregnancy
Specimen	urine	urine
Endpoint	colored lines	colored lines
Format	test strips in device	test strips in device
Methodology	membrane particle assay	membrane particle assay
Storage	15° to 30° C	15° to 30° C
Test Time	3 minutes	4 minutes
Sensitivity	25 mIU/ml	20 mIU/ml
Accuracy	≤99%	≥99%
Specificity	No interferences when tested with LH, FSH and TSH	No interferences
Standardization	WHO Third International Standard	WHO Third International Standard



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 18 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Patricia E. Bonness
Official Correspondent
Acon Laboratories, Inc.
3140-B Tilghman Street, Suite 215
Allentown, Pennsylvania 18104

Re: K983090
Trade Name: ACON™ Midstream Pregnancy Test
Regulatory Class: II
Product Code: LCX
Dated: September 2, 1998
Received: September 3, 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 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). 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.

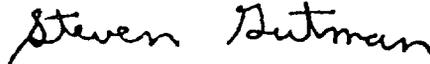
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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/dsma/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

Statement of Indications For Use

510(k) Number: K983090

Device Name: ACON™ Midstream Pregnancy Test

"Indications For Use" - ACON™ Midstream Pregnancy Test is intended for home use (over-the-counter) for the qualitative detection of hCG (human Chorionic Gonadotropin) in urine to aid in the determination of pregnancy.

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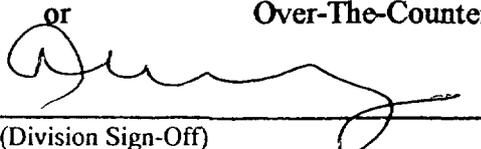
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109)

or

Over-The-Counter Use





(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K983090