JAN - 9 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123986

The primary purpose of this 510(k) submission is to expand the intended use claims to support use of the Actim PROM test in pregnant women greater than or equal to (≥) 29 weeks gestational age and use of vaginal swab samples collected without the use of a speculum in addition to the current sample type, swabs collected with the use of a speculum.

To establish substantial equivalence to the predicate, the Actim PROM test was compared to the previously cleared version of the Actim PROM test (510(k) K061886).

SUBMITTER
Alere Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074
Establishment Registration Number: 1221359

CONTACT PERSON
Angela Drysdale, VP Regulatory & Clinical Affairs – Infectious Disease
Phone: (207)-730-5737
Fax: (207)-730-5717
Angela.drysdale@alere.com

DATE PREPARED
January 7, 2014

TRADE NAME
Actim PROM

COMMON NAME
Rupture of Fetal Membranes (ROM) Rapid Diagnostic Test

CLASSIFICATION NAME
Urinary pH (non-quantitative) Test System (per 21 CFR 862.1550)

CLASSIFICATION
Class I

PRODUCT CODE
OAM

PANEL
Clinical Chemistry

PREDICATE DEVICE
Actim PROM (510(k) K061886)

DEVICE DESCRIPTION

The Actim PROM test is a rapid test to aid in diagnosis of premature rupture of fetal membranes in pregnant women who present with signs, symptoms or complaints suggestive of ROM. The test is based on lateral flow immunoassay. It utilizes two monoclonal antibodies to human IGFBP-1. One of the two antibodies is bound to blue latex particles (detecting antibody). The other antibody is immobilized as a test line on the membrane (catching antibody). The test strip (dipstick) is composed of the sample/conjugate pad, the membrane with test and control lines, and the absorbent pad assembled between plastic films. The upper film contains a test window. When the sample area of the dipstick is placed in an extracted sample, the dipstick absorbs liquid, which starts to flow up the dipstick. If the sample contains IGFBP-1 it binds to the antibody labeled with latex particles. The particles are carried by the liquid flow, and if IGFBP-1 is bound to them, they bind to the catching antibody. A blue line (test line) will appear in the result area if the concentration of IGFBP-1 in the sample exceeds the detection limit of the test. A second blue line, the control line, confirms correct operator performance of the test.

INTENDED USE

The Actim PROM test is a visually interpreted, qualitative immunoassay rapid test for the detection of amniotic fluid in cervicovaginal secretions during pregnancy. The Actim PROM test detects IGFBP-1, a major protein in amniotic fluid and a marker of the presence of amniotic fluid in a vaginal sample. The test is intended for prescription use in point of care and clinical laboratory settings to help diagnose the rupture of fetal membranes (ROM) in pregnant women $\geq$29 weeks gestation who present with signs, symptoms or complaints suggestive of ROM.

TECHNOLOGICAL CHARACTERISTICS

The Actim PROM test is a qualitative, lateral flow immunoassay intended to aid in the detection of ruptured fetal membranes in pregnant women. Detection of results is by visual inspection. The Actim PROM test is intended for use in the point-of-care and clinical laboratory setting.

There have been no changes made to the Actim PROM test. The device is physically the same as the current, 510(k) cleared Actim PROM test. The purpose of this submission is to expand the indication for use claims to include use of the device in pregnant women $\geq$29 weeks gestational age and to allow use of the device with vaginal swabs collected without use of a speculum.

PERFORMANCE SUMMARY

CLINICAL STUDY

The clinical performance of the Actim PROM test was established in a multi-center, prospective clinical study conducted at six US clinical sites over an 18 month period. A total of 222 pregnant women presenting with signs/symptoms suggestive of ROM were evaluated using the Actim PROM test and compared to results obtained from conventional clinical criteria. Subjects were considered clinically positive for PROM if amniotic fluid was seen leaking from the cervical os upon diagnostic speculum examination, or if two of the three following clinical signs were positive: visual pooling of fluid in the posterior fornix, positive nitrazine test or microscopic evidence of ferning. Actim PROM test performance was established relative to clinical diagnosis as determined by the conventional clinical criteria identified above.

Actim PROM test performance by sample type and gestational age versus clinical diagnosis, including 95% Confidence Intervals (CI), is presented below.

Table 1: Actim PROM Test Performance vs. Clinical Diagnosis - Overall Results - ≥ 29 Weeks Gestational Age

	N	Sensitivity (95% Confidence Intervals)	Specificity (95% Confidence Intervals)
≥ 29 weeks (Without Speculum)	222	90.1% (100/111) (95% CI: 83.1-94.4%)	91.0% (101/111) (95% CI: 84.2-95.0%)
≥ 29 weeks (With Speculum)	220*	95.5% (105/110) (95% CI: 89.8-98.0%)	86.4% (95/110) (95% CI: 78.7-91.6%)

*2 invalid test results (control lines were not visible) were not included in the analysis for sample collected with speculum.

Performance of the Actim PROM test was analyzed based on a patient's gestational age at the time of sample collection.

Table 2: Actim PROM Test Performance vs. Clinical Diagnosis – ≥ 29 to 34 Weeks Gestational Age

	N	Sensitivity (95% Confidence Intervals)	Specificity (95% Confidence Intervals)
≥ 29 to 34 weeks (Without Speculum)	97	95.7% (44/46) (95% CI: 85.5-98.8%)	96.1% (49/51) (95% CI: 86.8-98.9%)
≥ 29 to 34 weeks (With Speculum)	96*	95.7% (44/46) (95% CI: 85.8-98.8%)	90.0% (45/50) (95% CI: 78.6-95.7%)

*1 invalid test result (control line was not visible) was not included in the analysis for sample collected with speculum.

ANALYTICAL STUDIES

REPEATABILITY

A panel of specimens consisting of samples of different IGFBP-1 concentration levels was evaluated for intra-assay precision. The samples were tested with 10 replicates during the same day using three different lots of the Actim PROM test. Repeatable results were obtained.

REPRODUCIBILITY

A study of the Actim PROM test was conducted at three separate sites using panels of blind coded specimens containing negative (0µg/l of IGFBP-1), high negative (5µg/l of IGFBP-1), moderate negative (12.5µg/l of IGFBP-1), low positive (20µg/l of IGFBP-1), moderate positive (25µg/l of IGFBP-1), and high positive (30, 50, and 100µg/l of IGFBP-1) specimens. Test operators (n=9) tested each level multiple times over a period of five days. A total of 360 tests were performed (120 per site) with a total of 45 tests per sample. The overall reproducibility of the Actim PROM test is 97% (350/360) with no significant differences within runs (replicates tested by one operator), between runs (five different days), between sites (three sites) or between operators (nine operators).

ANALYTICAL SENSITIVITY

The analytical sensitivity (detection limit) of the Actim PROM test was identified by evaluating different concentrations of IGFBP-1 in extracted sample on three different lots of the Actim PROM test. Two different operators each interpreted ten devices run at each concentration under various lighting conditions for a total of 60 determinations per level. The Actim PROM test limit of detection (100% positive) is approximately 25 µg/L of IGFBP-1 in extracted sample. The measuring range of the Actim PROM test is approximately 25-500,000 µg/L in extracted sample. It should be noted that positive results could be observed for extracted samples with IGFBP-1 at <25 ug/L.

ANALYTICAL SPECIFICITY

Analytical specificity (cross-reactivity) was tested with human IGFBP proteins at concentrations ranging from 10-5,000 µg/L of each protein in extracted sample were tested. No cross-reactivity was seen using human IGFBP-2, -3, -4, -5 and -6 proteins. The Actim PROM test is specific to human IGFBP-1.

INTERFERING SUBSTANCES

The following drugs, shower and bath products, odor control products, and vaginal pathogens were tested with Actim PROM test and were found not to affect Actim PROM test performance.

Interfering Substance:	Concentration Tested
Pevaryl (active ingredient: econatzol.nitras)	30 mg/ml
Gyno-Trosyd (tioconazol)	20 mg/ml
Flagyl (metronidazole)	100 mg/ml
Canesten (clotrimazol)	40 mg/ml
Personal Lubricant	50%
Baby Oil	50%
Baby Powder	50%
Feminine Deodorant Suppositories	50%
RepHresh Vaginal Gel	50%
Feminine Deodorant Film	50%
Candida albicans	11.2×10^8 CFU/ml
Gardnerella vaginalis	8.6×10^8 CFU/ml
Neisseria gonorrhea	10.6×10^8 CFU/ml
Chlamydia trachomatis	*
HSV-1	*
HSV-2	*

* Supplied as high concentration from the University of Turku, Finland

Semen and pregnancy urine were tested with the Actim PROM test. No interference of these substances was observed with the performance of the Actim PROM test. Whole blood with concentrations corresponding to typical pregnancy levels of IGFBP-1 was tested and did not affect Actim PROM test performance.

Samples with different pH levels (pH levels from 3.5-8.5) were tested with the Actim PROM test and were found not to affect Actim PROM test performance.

Signed Angela Drysdale Date 1/7/2014
Angela Drysdale
VP, Regulatory & Clinical Affairs – Infectious Disease
Alere Scarborough, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2014

ALERE SCARBOROUGH, INC
ANGELA DRYSDALE
VP, REG/CLINICAL AFFAIRS - INFECTIOUS DISEASE
10 SOUTHGATE ROAD
SCARBOROUGH ME 04074

Re: K123986
Trade/Device Name: Actim Prom, Actim Prom Controls
Regulation Number: 21 CFR 862.1550
Regulation Name: Urinary pH (nonquantitative) test system
Regulatory Class: I, meets limitations to exemption in 21 CFR 862.9(c)(9)
Product Code: OAM
Dated: December 23, 2013
Received: December 24, 2013

Dear Ms. Drysdale:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123986

Device Name: Actim® PROM

Indications for Use:

The Actim PROM test is a visually interpreted, qualitative immunoassay rapid test for the detection of amniotic fluid in cervicovaginal secretions during pregnancy. The Actim PROM test detects IGFBP-1, a major protein in amniotic fluid and a marker of the presence of amniotic fluid in a vaginal sample. The test is intended for prescription use in point of care and clinical laboratory settings to help diagnose the rupture of fetal membranes (ROM) in pregnant women ≥ 29 weeks gestation who present with signs, symptoms or complaints suggestive of ROM.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123986