K102760

AUG - 3 2011

510(k) Summary

1- Name and Address of Submitter

The submitter's name: Atlas Medical.

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Email: quality.assurance4@atlas-site.co.uk
Contact person: Noor Al-ahwal (QA Manager)

This 510(k) summary was prepared on April 26th, 2011.

2- The name of the device

Trade Name:	Atlas Home Pregnancy Test (Midstream format).
Common Name:	Pregnancy Test Kit, OTC.
Classification Name:	Kit, Test, Pregnancy, hCG, Over The Counter.
Device classification (Regulation Number): 21 CFR Part 862.1155.	
Regulatory Class:	II
Product Code:	LCX.
Panel:	75 - Clinical Chemistry.
Format:	Midstream.

3- Equivalence legally marketed device:

Atlas Home Pregnancy Test (Midstream Format) has been determined to be substantially equivalent to ACON™ One Step Test Device (K993317) currently in commercial distribution by Acon Laboratories, Inc.

4- Device description:

Atlas Home Pregnancy Test (Midstream Format) is an OTC single use rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

5- Intended use:

Atlas Home Pregnancy Test, Midstream (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in the urine to aid in the early detection of pregnancy.

6- Test Format:

Atlas Home Pregnancy Test is a Midstream format.

7- Test Principle:

Atlas Home Pregnancy Test (Midstream Format) is a rapid qualitative chromatographic assay, utilizes a combination of antibodies including hCG antibody to detect elevated levels of hCG. The test consists of a membrane coated with a polyclonal anti-hCG Abs as a test line, colored conjugate of mouse anti-hCG Abs colloidal gold conjugate act as a conjugate releasing pad, and the control line which contains a monoclonal goat anti-mouse Abs. When the urine sample is applied it will react with the colored conjugate in the conjugate releasing pad, then the mixture migrates upwards on the membrane chromatographically to react with hCG Abs on the membrane and generates a colored band, which indicates a positive result. As the mixture continues to migrate across the membrane to the goat anti-mouse region colored band will always appear to serve as a procedural control and to show that the test has been performed properly.

8- Major ingredients of Atlas Home Pregnancy Test (Midstream Format):

- Mouse anti- hCG
- Polyclonal anti-hCG Abs
- Monoclonal goat anti-mouse Abs
- Colloidal gold conjugated with mouse anti-hCG Abs.

9- Comparison with predicate device

Feature Comparison of Atlas Home Pregnancy Test (Midstream Format) with ACON™ Midstream Pregnancy Test.

Parameter	**Atlas Home Pregnancy Test (Midstream Format)**	**ACON™ One Step Pregnancy Test Device. (K993317)**
Intended Use	Home Use (OTC) test for the qualitative detection of human chorionic gonadotropin (hCG) in urine	Home Use (OTC) test for the qualitative detection of human chorionic gonadotropin (hCG) in urine
Indication for Use	Early detection of pregnancy	Early detection of pregnancy.
Specimen	Urine	Urine
Format	Test strip in a midstream device.	Test strip in a plastic device.
Methodology	Colloidal Gold Immunoassay (Membrane particle assay)	Colloidal Gold Immunoassay (Membrane particle assay)
Storage	36-86°F	59-86°F
Test Time	3 minutes.	3 minutes.

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Detection limit	25 mIU/ml	25 mIU/ml
Accuracy	≥99%	≥99%
Specificity	No interference when tested with FSH, LH & TSH	No interference when tested with FSH, LH & TSH
Standardization	WHO Third International Standard.	WHO Third International Standard.

The above comparison is based on the Performance Testing – Bench study and clinical studies results included in this file. The study includes results accuracy conducted for both tests.
The results show that Atlas Home Pregnancy Test compares well with the ACON™ One Step Pregnancy Test.

Conclusion
Atlas Home Pregnancy Test (Midstream Format) is found to be substantially equivalent to the predicate device (ACON™ One Step Pregnancy Test).

Risk Analysis as per ISO14971 "Medical Devices — Application of risk management to medical devices" has been conducted on Atlas Home Pregnancy Test (Midstream Format) and had showed that possible risks encountered with the use of the product is very minimal and the benefits outweigh risks by far.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 03 2011

Atlas Medical
c/o Nour Al-ahwal
King Abdullah II Industrial Estate
Street 19, Sahab Free Zone Area
P.O. Box 201
Amman, Jordan 11512

Re: k102760
Trade Name: Atlas Home Pregnancy Test (Midstream Format)
Regulation Number: 21 CFR §862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: July 23, 2011
Received: July 26, 2011

Dear Nour Al-ahwal:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K102760

Device Name: **Atlas Home Pregnancy Test. (Midstream Format)**

Indication for Use:

Atlas Home Pregnancy Test (Midstream Format) is a home use (OTC) rapid chromatographic immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in the urine to aid in the early detection of pregnancy.

Prescription Use NO **And/or** **Over The Counter Use** Yes
(21 CFR Part 801 Subpart D) **(21 CFR Part 801 Subpart C)**

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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