K112315

APR 23 2012

510k Summary

Submitted By:	NewScen Coast Bio-Pharmaceutical Co.,Ltd. No 65. 6th Street TEDA, Tianjin, China, P.C: 300457 Telephone: 86-22-25321648-867 Fax: 86-22-25321647
Submission Contact:	Chandravadan Patel, Ph.D.
Date Prepared:	Feb 23, 2012
Device Trade Name:	y.b.t. Pregnancy Test Cassette y.b.t. Pregnancy Test Strip
Common Name:	Urine Pregnancy Test
Predicate Device:	ACON™ hCG One Step Pregnancy Test Strip (Urine) (K993203)
Product Code:	JHI
Device Classification / Name:	21 CFR§862.1155 / Human Chorionic Gonadotropin (hCG) Test System, Class II
Intended Use:	The y.b.t. Pregnancy Test is an immuno chromatographic assay for the qualitative determination of HCG in human urine. The test is intended for use as an aid in the early detection of pregnancy.
Physiologic Basis of the Test:	Human Chorionic Gonadotropin is a hormone produced by the placenta shortly after implantation. Since hCG is present in the urine of pregnant women, it is an excellent marker for confirming pregnancy.
Device Description:	The test is available in two formats: strip and cassette.Both of them are intended for prescription use. Both of them have the same memebrane format, reagents and flow characteristics. Devices are packaged one device per pouch with 1 devices per kit.

Device Comparison

Table 1. Device Comparison of NewScen y.b.t Pregnancy Test and Acon Pregnancy Test

Features	NewScen y.b.t Pregnancy Test (Proposed)	Acon Pregnancy Test Strip (K993203)
Intended Use	The y.b.t. Pregnancy Test is an immuno chromatographic assay for the qualitative determination of HCG in human urine. The test is intended for use as an aid in the early detection of pregnancy.	The Acon Pregnancy Test Strip is a one-step immunoassay for the qualitative detection of HCG in Urine for the early detection of pregnancy. The test is intended for use by health care professionals.
Analyte	Human Chorionic Gonadotropin	Human Chorionic Gonadotropin
Specimen	Urine	Urine or serum
Format	Lateral-flow immunoassay	Lateral-flow immunoassay (strip)
Total steps	1	1
Read Time	5 minutes	3 or 5 minutes
Sensitivity	25 mIU/ml	25 mIU/ml
Test Interpretation	Red procedural control line Pink-to-red line	Red procedural control line Pink-to-red line
Test Strip Components	Test Line* Monoclonal Beta anti-hCG antibody is immobilized in the test zone on the nitrocellulose membrane	Test Line* Monoclonal Beta anti-hCG antibody is immobilized in the test zone on the nitrocellulose membrane
	Indicator Monoclonal Alpha anti-HCG antibody coupled to red-colored gold particles is incorporated into the conjugate Pad	Indicator Monoclonal Alpha anti-HCG antibody coupled to red-colored gold particles is incorporated into the conjugate Pad
	Control Line* Goat anti-mouse antibody is spotted in the control zone on the nitrocellulose membrane.	Control Line* Goat anti-mouse antibody is spotted in the control zone on the nitrocellulose membrane.

***Note**: The monoclonal antibodies used for the Test Line and the Indicator in the y.b.t Pregnancy Test are identical to those used in the predicate Acon Pregnancy Test Strip. The components that generate the Control Line are also identical.

Table 2. Components Comparison of y.b.t HCG Strip and y.b.t HCG Cassette

Features	Y.b.t Pregnancy Test (Cassette)	Y.b.t Pregnancy Test (Strip)
Antibody	T-line: mouse anti HCG-Beta, Clone # 9008	Same
	C-line: goat anti mouse IgG,	Same
	Conjugation, Mouse anti HCG-Alpha, Clone # 9001	Same

Specimen pad	Non-woven cloth	Same
Conjugate Gold Pad	Non-woven cloth, Conjugate gold	Same
NC membrane	Nitrocellulose membrane	Same
Absorbent pad	Absorbent paper	Same
PVC baseplate	PVC plate	Same
Buffer	PBS	Same
Cassette	No	Cassette
Colorful paper	Colorful Paper	No
Max line	Colorful Paper	No

Summary of Performance Data:

SESITIVITY

The test will detect hCG in urine at concentration of 25 mIU/ml and higher. This sensitivity level has been confirmed with hCG standards (25, 50, 250, 2500, and 500,000 mIU/ml) in urine calibrated against the WHO Third I.S.. Occasionally, specimens containing less than 25 mIU/ml hCG can give positive results.

SPECIFICITY

Menopausal urine samples

A study was performed using urine specimens from 20 postmenopausal women. Urine of postmenopausal women can interfere with pregnancy testing due to elevated concentrations of gonadotropic hormone structurally similar to hCG. All 20 samples tested negative with the y.b.t. hCG Card.

Potentially interfering substances

The following substances did not interfere with hCG testing using y.b.t. hCG Card when added to urine samples containing 0 mIU/ml and 25 mIU/ml hCG:

Acetaminophen	20mg/dl	Ascorbic acid	20mg/dl
Acetylsalicylic acid	20mg/dl	Ampicilline	20mg/dl
Atropine	20mg/dl	Caffeine	20mg/ml
Cortisol	200ng/ml	Albumin	2,000mg/dl
DHEAS	500ng/ml	Estradiol (E-2)	25ng/ml
Estriol (E-3)	25ng/ml	Gentisic acid	20mg/dl
Glucose	2,000mg/dl	Tetracycline	20mg/dl
Uric acid	10mg/dl	Bilirubin	1000mg/dl
Hemoglobin	1mg/dl		

Cross reactive glycoprotein hormones

The following hormones structurally related to hCG did not interfere with hCG testing using the y.b.t. hCG Card when added to urine specimens at the concentrations indicated below:
Luteinizing hormone 100-1000 mIU/ml,
Follicle stimulating hormone 100-1,000 mIU/ml
Tyroid stimulating hormone 100-1,000 mIU/ml

Method Comparison

60 positive and 60 negative patient urine specimens confirmed with routine diagnostic method were tested against y.b.t pregnancy test strip at two certified hospital. The results showed 100% consistence.

	Positive Urine	Negative Urine	Total
y.b.t (+)	60	0	60
y.b.t (-)	0	60	60
Total	60	60	120

Positive agreement: (60+0)/60=100%
Negative agreement:: (0+60)/60=100%
Specificity: (60+60)/(60+60)=100%

PRECISION

Intra-assay

In the study, eleven replicate assays were performed with each of three specimens containing 0, 25, and 250 mIU/ml hCG. Correct negative and positive results were registered in 100% of the assays.

Inter-assay

The study involved the same three specimens containing 0, 25, and 250 mIU/ml hCG. The samples were analyzed in eleven independent assays with y.b.t. hCG Card originating from three different lots at different times during two months. Again, expected negative and positive results were registered in 100% of the assays.

STORAGE AND STABILITY

Store Y.b.t. Preganacy Test Strip at temperature ranges 2-30 °C in the sealed pouch. Refer to the expiration date for stability. Do not freeze. Use the strip immediately once the sealed pouch is opened.

Conclusion:

The result of these studies demonstrate that y.b.t pregnancy test is substantially equivalent with the predicate Acon Pregnancy Test

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

NewScen Coast Bio-Pharmaceutical Co., Ltd
c/o Chandravadan Patel, Ph.D.
2117 Claney Ct.
Simi Valley, CA 93065

APR 2 3 2012

Re: k112315

Trade/Device Name: y.b.t. Pregnancy Test Strip; y.b.t. Pregnancy Test Cassette
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (hCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: April 9, 2012
Received: April 16, 2012

Dear Dr. Patel:

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 class II (Special Controls), 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). This letter will allow you to begin marketing your device as described in your Section 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), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): k112315

Device Name: The y.b.t Pregnancy Test Strip

Indications for Use:

The y.b.t. Pregnancy Test Strip is an immunochromatographic assay for the qualitative determination of HCG in human urine. The test is intended for use as an aid in the early detection of pregnancy.

Prescription Use ___x___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR801 Subpart D)		(21 CFR801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices(OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k112315

Indications for Use

510(k) Number (if known): k112315

Device Name: The y.b.t Pregnancy Test Cassette

Indications for Use:

The y.b.t. Pregnancy Test Cassette is an immunochromatographic assay for the qualitative determination of HCG in human urine. The test is intended for use as an aid in the early detection of pregnancy.

Prescription Use ___x___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR801 Subpart D)		(21 CFR801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices(OIVD)

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