K051963

IV. 510(k) SUMMARY (As Required by Section 807.92(c)

NOV 2 3 2005

(A) OWNER'S NAME [807.92(a)(1)]

Owner's Name:	Victor J. Santos
	President
Company:	Natureplex, LLC
Address:	3791 Airpark Street
	Memphis, TN 38118
Phone:	(866) 323-0107
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Contact Person:	Victor J. Santos
Date Prepared:	September 15, 2005

(B) NAME OF THE DEVICE [807.92(a)(2)]

Trade Name:	BE CERTAIN™ Home Pregnancy Test
Common Name:	hCG Pregnancy Test
Classification Name:	FDA Product Code: LCX
	Kit, Test, Pregnancy, hCG, Over-the-Counter

(C) LEGALLY MARKETED DEVICE [807.92(a)(3)]

Substantial equivalence is being claimed with the following legally marketed device: E.P.T. Pregnancy Test (K# 033658).

(D) DESCRIPTION OF THE DEVICE [807.92(a)(4)]

The BE CERTAIN™ Home Pregnancy Test is an hCG assay, comprising of a rapid one-step test, based on an immunochromatographic technology. The test is made up of a membrane with an absorbent pad overlapping a strip of fiber glass paper that is impregnated with a lyophilized colloidal conjugate of gold particles and monoclonal solid phase antibodies to hCG. Other absorbent pads at the end of the assay absorb excess sample fluid. The urine sample is introduced into the device and proceeds through the absorbent pad, then laterally onto a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the hCG antigen will attach to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-hCG monoclonal antibody affixed on the test zone ("T") will bind the hCG-gold conjugate complex, forming a pink line ("T"). All samples will cause a pink colored line to appear in the control zone ("C"). This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates that the test has been carried out correctly. In less than 5 minutes, levels of hCG as low as 25mlU/ml can be detected.

(E) INTENDED USE OF THE DEVICE [807.92(a)(5)]

The BE CERTAIN™ Home Pregnancy Test is intended for the qualitative identification of the elevated level of Human Chorionic Gonadotrophin (hCG) in urine to aid in the determination of pregnancy. It is for over-the-counter consumer use.

(F) TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE AS COMPARED TO PREDICATE DEVICE [807.92(a)(5)]

The BE CERTAIN™ Home Pregnancy Test is substantially equivalent to the E.P.T.® Pregnancy Test [#K033658] based on the following characteristics:

ITEM	BE CERTAIN™ Home Pregnancy Test	E.P.T.® Pregnancy Test
Intended Use	Qualitative identification of pregnancy hormone i.e., Human Chorionic Gonadotrophin (hCG)	Qualitative identification of pregnancy hormone i.e., Human Chorionic Gonadotrophin (hCG)
Indications for Use	Determination of pregnancy	Determination of pregnancy
Target Population	Pregnant women	Pregnant women
Where Used	Home	Home
Formats Available	Casette	Casette
Sterility	Non-sterile	Non-sterile
Specimen Type	Human urine	Human urine
Antibodies	• Polyclonal anti-mouse IgG • Anti-β-hCG antibody and anti-α hCG monoclonal antibody	• Polyclonal anti-mouse IgG • Anti-β-hCG antibody and anti-α hCG monoclonal antibody
Cutoff	25 mIU/ml	25 mIU/ml
Storage Temperature	4 – 30° C	2 – 30° C
Read Time	3 –5 Minutes	2 –10 Minutes

(G) NON-CLINICAL PERFORMANCE DATA [807.92(b)(1)] AND CONCLUSIONS FROM NON-CLINICAL TESTS [807.92(b)(3)]

(1) SENSITIVITY/DETECTION LIMIT DATA

To determine the sensitivity/detection limit of the BE CERTAIN™ Home Pregnancy Test, the analyte concentration of Human Chorionic Gonadotrophin (hCG) at which 95% of the test results are positive was determined. This was carried out by spiking human urine samples from 30 different non-pregnant male or female subjects with different concentrations of hCG. A total of five different samples at each concentration of hCG was blindly labeled and tested with the BE CERTAIN™ Home Pregnancy Test. The results of this study are presented in Table 1 below.

Table 1. Sensitivity/Detection Limit Data for the BE CERTAIN™ Home Pregnancy Test.

hCG CONCENTRATION	POSITIVE	NEGATIVE
0 mIU/ml	0 of 5	5 of 5
12.5 mIU/ml	1 of 5	4 of 5
18.75 mIU/ml	3 of 5	2 of 5
25 mIU/ml	5 of 5	0 of 5
50 mIU/ml	5 of 5	0 of 5
100 mIU/ml	5 of 5	0 of 5

The sensitivity of the BE CERTAIN™ Home Pregnancy Test was tested by spiking thirty negative urine samples with varying concentrations of hCG. None of the samples (0%) for 0 mIU/ml of hCG had tested positive. Conversely, 1 out of 5 (20%) and 3 out of 5 (60%) for 12.5 mIU/ml and 18.75 mIU/ml of hCG, respectively, had tested positive. All samples (100%) for 25 mIU/ml, 50 mIU/ml, and 100 mIU/ml had tested positive with the BE CERTAIN™ Home Pregnancy Test. The sponsor claims a detection limit of 25 mIU/ml for the BE CERTAIN™ Home Pregnancy Test.

(2) SPECIFICITY DATA INCLUDING LH, FSH, AND TSH

To determine the specificity of the BE CERTAIN™ Home Pregnancy Test, in terms of its cross-reactivity with high physiologic concentration of Human Luteinizing Hormone (hLH), Human Follicle Stimulating Hormone (hFSH), and Human Thyroid Stimulating Hormone (hTSH), human urine samples from a total of 45 different normal, non-pregnant females or males were spiked with varying concentration of hLH, hFSH, and hTSH, with or without hCG. The results of this study are presented in Table 2 below.

Table 2. Specificity Data for the BE CERTAIN™ Home Pregnancy Test.

HORMONES		5 mls URINE		5 mls URINE + 10 mIU/ml hCG		5 mls URINE + 50 mIU/ml hCG	
		(+)	(-)	(+)	(-)	(+)	(-)
hLH	100 mIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
	300 mIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
	500 mIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
hFSH	100 mIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
	300 mIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
	500 mIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
hTSH	750 µIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
	1,000 µIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5
	1,250 µIU/ml	0 of 5	5 of 5	0 of 5	5 of 5	5 of 5	0 of 5

For the human urine samples spiked with hLH, hFSH, and hTSH at varying concentrations, none of the samples (0%) showed a positive reading with the BE

CERTAIN™ Home Pregnancy Test. Similarly, for the human urine + 10 mIU/ml hCG samples that were spiked with hLH, hFSH, and hTSH at varying concentrations, none of the samples (0%) showed a positive reading with the BE CERTAIN™ Home Pregnancy Test. Conversely, for the human urine + 50 mIU/ml hCG samples that were spiked with hLH, hFSH, and hTSH at varying concentrations, all samples (100%) showed a positive reading with the BE CERTAIN™ Home Pregnancy Test as would have been expected since the BE CERTAIN™ Home Pregnancy Test has been demonstrated to have a detection limit of hCG at 25 mIU/ml.

(3) INTERFERING SUBSTANCES DATA

To determine the interference by certain exogenous compounds, human urine samples from non-pregnant female or male subjects were spiked with prescription/OTC drugs, chemical analytes, biological analytes, as well as titrated for pH, and tested with the BE CERTAIN™ Home Pregnancy Test. The results of the analyte interfering study are presented in Table 3 below.

Table 3: Analyte Interfering Data for the BE CERTAIN™ Pregnancy Test.

ANALYTES	**5 mls URINE**		**5 mls URINE + 50 mIU/ml hCG**	
	(+)	(-)	(+)	(-)
Acetaminophen (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Aspirin (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Ampicillin (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Tetracycline (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Caffeine (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Ascorbic Acid (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Glucose (2000 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Protein (2000 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Albumin (20 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Bilirubin (2 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Hemoglobin (1 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3
Triglyceride (800 mg/dL)	0 of 3	3 of 3	3 of 3	0 of 3

The results of the pH interfering study are presented in Table 4 below.

Table 4: pH Interfering Data for the BE CERTAIN™ Pregnancy Test.

pH	**5 mls URINE**		**5 mls URINE + 50 mIU/ml hCG**	
	(+)	(-)	(+)	(-)
pH 3	0 of 1	1 of 1	1 of 1	0 of 1
pH 5	0 of 1	1 of 1	1 of 1	0 of 1
pH 7	0 of 1	1 of 1	1 of 1	0 of 1
pH 10	0 of 1	1 of 1	1 of 1	0 of 1

No interference was observed by the exogenous compounds tested above, as observed in this study using the BE CERTAIN™ Home Pregnancy Test. Further, human urine samples with pH ranges between 3-10 did not adversely affect the test and produced the expected results.

(H) CLINICAL PERFORMANCE DATA [807.92(b)(2)] AND CONCLUSIONS FROM CLINICAL TESTS [807.92(b)(3)]

(1) COMPARISON STUDY USING THE DIP METHOD

Spiked human urine samples from 100 normal, non-pregnant females were tested in order to determine the correlation of the new test, the BE CERTAIN™ Pregnancy Test, when used by subjects using a dip method, with that of the BE CERTAIN™ Pregnancy Test, when tested by a professional user, as well as with that of a reference standard, the E.P.T.® Pregnancy Test (i.e., the predicate device; previously cleared under 510(k) #K033658) The results of this study are as follows:

Table 5. Concordance of BE CERTAIN™ Home Pregnancy Test (Tested by End User) Compared with BE CERTAIN™ Home Pregnancy Test (Tested by Professional User), Both Following a Urine Dip Method.

		BE CERTAIN™ (Prof. User)		
		(+)	(-)	
BE CERTAIN™ (End User)	(+)	61	0	61
	(-)	0	39	39
Total		61	39	100

Based on the above 2x2 analysis, the Concordance of the BE CERTAIN™ Home Pregnancy Test when tested by the End User and the Professional User is 100/100= 100%, with a 95% confidence interval of 96% - 100%. The sensitivity of the BE CERTAIN™ Home Pregnancy Test is 61/61= 100%, with a 95% confidence interval of 94% - 100%. Finally, the Specificity of the BE CERTAIN™ Home Pregnancy Test is 39/39= 100%, with a 95% confidence interval of 91% - 100%.

Table 6. Concordance of BE CERTAIN™ Home Pregnancy Test (Tested by End User) Compared with E.P.T.® Pregnancy Test (Tested by Professional User), Both Following a Urine Dip Method

		E.P.T.® (Prof. User)		
		(+)	(-)	
BE CERTAIN™ (End User)	(+)	61	0	61
	(-)	1	38	39
Total		62	38	100

Based on the above 2x2 analysis, the Concordance of the BE CERTAIN™ Home Pregnancy Test when tested by the End User, as compared with the predicate device, the

E.P.T.® Pregnancy Test as tested by the Professional User is 99/100= 99%, with a 95% confidence interval of 95% - 100%. The sensitivity of the BE CERTAIN™ Home Pregnancy Test is 61/62= 98.3%, with a 95% confidence interval of 91% - 100%. Finally, the Specificity of the BE CERTAIN™ Home Pregnancy Test is 38/38= 100%, with a 95% confidence interval of 91% - 100%.

The above studies show that the BE CERTAIN™ Home Pregnancy Test, when used by either an end user or a professional user following a urine dip method have a strong concordance. Likewise, the BE CERTAIN™ Home Pregnancy Test has a strong concordance with the predicate device, the E.P.T.® Pregnancy Test.

(2) COMPARISON STUDY USING THE URINE DROP~~STREAM~~ METHOD

Spiked human urine samples from 50 normal, non-pregnant females were tested in order to determine the correlation of the new test, the BE CERTAIN™ Pregnancy Test, when used by subjects using a urine drop~~stream~~ method, with that of the reference standard, the E.P.T.® Pregnancy Test (i.e., the predicate device; previously cleared under 510(k) #K033658). The results of this study are as follows:

Table 7. Concordance of BE CERTAIN™ Home Pregnancy Test (Tested by End User Using a Urine Drop~~Stream~~ Method) Compared with E.P.T.® Pregnancy Test (Tested by Professional User Using a Urine Dip Method)

		E.P.T.® (Urine Dip)		
		(+)	(-)	
BE CERTAIN (Urine Stream)	(+)	27	0	27
	(-)	0	23	23
Total		27	23	50

Based on the above 2x2 analysis, the Concordance of the BE CERTAIN™ Home Pregnancy Test when tested by the End User using a urine drop~~stream~~ method, as compared with the E.P.T.® Pregnancy Test (Tested by Professional User using a Urine Dip Method) is 50/50= 100%, with a 95% confidence interval of 93% - 100%. The sensitivity of the BE CERTAIN™ Home Pregnancy Test is 27/27= 100%, with a 95% confidence interval of 88% - 100%. Finally, the Specificity of the BE CERTAIN™ Home Pregnancy Test is 23/23= 100%, with a 95% confidence interval of 86% - 100%.

As expected, the BE CERTAIN™ Pregnancy Test, when tested using the urine drop~~stream~~ method, had produced equivalent results with that of the dip urine method.

(l) OTHER INFORMATION [807.92(d)]

(1) EXPECTED VALUES

The BE CERTAIN™ Home Pregnancy Test is capable of detecting pregnancy by the first day of the missing period and no sooner.

(2) CALIBRATION

The BE CERTAIN™ Home Pregnancy Test is calibrated against the WHO 3rd International Standard for hCG.

(3) QUALITY CONTROL

The BE CERTAIN™ Home Pregnancy Test has built in Quality Control Features. After addition of the urine sample, these colored bands migrate along the membrane at the leading edge of the dye conjugate and are "removed" from the test strip completely.

When the test is complete, the end user will see a pink-purple colored band in the "C" area of the test strip on negative samples and a pink-purple colored band in the "T" and "C" area on positive samples. The appearance of the CONTROL ("C") band indicates that the test strip is performing properly and serves as a procedural internal control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 23 2005

Mr. Victor J. Santos
President
Natureplex, LLC.
3791 Air Park Street
Memphis, TN 38118

Re: k051963
Trade/Device Name: BE CERTAIN Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: November 16, 2005
Received: November 17, 2005

Dear Mr. Santos:

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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510 (k) Number: K051963

Device Name: BE CERTAIN Pregnancy Test

"Indications for Use": The BE CERTAIN Pregnancy Test is intended for the qualitative identification of the elevated level of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy. It is for over-the-counter consumer use.

Prescription Use_____ AND/OR Over-The-Counter Use____X___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051963