Anhui DEEPBLUE Medical Technology Co. LTD.
℅ Boyle Wang
Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K240242
Trade/Device Name: HCG Home Use Pregnancy Test Strip (Colloidal Gold), HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Midstream (Colloidal Gold).
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin
Regulatory Class: Class II
Product Code: LCX
Dated: September 2, 2024
Received: September 5, 2024

Dear Boyle Wang:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2024.10.11 11:00:20 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240242

Device Name
HCG Home Use Pregnancy Test Strip (Colloidal Gold)
HCG Home Use Pregnancy Test Cassette (Colloidal Gold)
HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

Indications for Use *(Describe)*

The HCG Home Use Pregnancy Test Strip (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
The test strip is designed for over-the-counter use.
Important note regarding positive results: This test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.
This device is intended for home use only.

The HCG Home Use Pregnancy Test Cassette (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
The test cassette is designed for over-the-counter use.
Important note regarding positive results: This test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.
This device is intended for home use only.

The HCG Home Use Pregnancy Test Midstream (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
The test midstream is designed for over-the-counter use.
Important note regarding positive results: This test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.
This device is intended for home use only.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

K240242

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

A. Submitter's Information

Name: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
Address: No.777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-551- 65326797
Contact: Ms. Fengling Chen

B. Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date prepared: Oct.11th,2024

C. Device Information

Trade/Device name: HCG Home Use Pregnancy Test Strip (Colloidal Gold),
HCG Home Use Pregnancy Test Cassette (Colloidal Gold),
HCG Home Use Pregnancy Test Midstream (Colloidal Gold)
Common name: Human Chorionic Gonadotropin (HCG) test
Product Code: LCX: Kit, Test, Pregnancy, hCG, over the counter
Classification: Class II
Regulation Number: 21 CFR 862.1155
Panel: 75-Clinical Chemistry

D. Predicate Device Information

Predicate Device#:
Manufacturer: Safecare Biotech (Hangzhou) Co., Ltd.

Trade/Device Name: hCG Urine Test Strip
hCG Urine Test Cassette
hCG Urine Test Midstream
510(k) number: K200133

E. Device Description

The HCG Home Use Pregnancy Test Strip (Colloidal Gold), HCG Home Use Pregnancy Test Cassette (Colloidal Gold) and HCG Home Use Pregnancy Test Midstream (Colloidal Gold) utilize a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The detection method is to observe the formation of colored lines when testing urine samples with test devices. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-HCG-colored conjugate and form a red colored line at the test line region of the membrane. The absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region if the test has been performed properly. HCG Pregnancy Test will be sold in three different formats: Cassette, Strip, and Midstream. The Test Strip and Midstream format contain a test device sealed in a desiccated aluminum pouch and an Instruction. The Cassette format contains a test device, a dropper, a collection container and an Instruction.
The test uses two red lines to indicate results. Two distinct red lines appear in the control region (C) and test region (T) means the test is “positive”. Only one red line appears in the control region(C). No apparent line in the test region (T). means the test is “negative”. If No coloured line appears in the control region (C), or if there is no color band in control region (C) even there is a band in the test region (T),this means “invalid” test result.

F. Indication for Use Statement

The HCG Home Use Pregnancy Test Strip (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
The test strip is designed for over-the-counter use.

Important note regarding positive results: This test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.

This device is intended for home use only.

The HCG Home Use Pregnancy Test Cassette (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

The test cassette is designed for over-the-counter use.

Important note regarding positive results: This test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.

This device is intended for home use only.

The HCG Home Use Pregnancy Test Midstream (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
The test midstream is designed for over-the-counter use.

Important note regarding positive results: This test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare providers, especially when making decisions about future medical care.

This device is intended for home use only.

G. Technological Characteristic Comparison Table

Item	Subject Device (K240242)	Predicate Device (K200133)
Product Name	HCG Home Use Pregnancy Test Strip (Colloidal Gold), HCG Home Use Pregnancy Test Cassette (Colloidal Gold), HCG Home Use Pregnancy Test Midstream (Colloidal Gold)	hCG Urine Test Strip hCG Urine Test Cassette hCG Urine Test Midstream
Intended Use	Aid in early detection of pregnancy	Early detection of pregnancy
Intended User	OTC use	OTC use
Sample Matrix	Urine	Same
Test Principle	Immunochromatographic assay	Immunochromatographic assay
Read time	5 minutes	3-5 minutes
Traceability	WHO International Standard 5th WHO Chorionic Gonadotrophin	Same
Format	Strip, Cassette, Midstream	Strip, Cassette, Midstream
Result	Qualitative	Qualitative
Antibodies	Monoclonal HCG-α antibody and goat anti-mouse IgG polyclonal antibody on the nitrocellulose mem-brane with colloidal gold marked anti-HCG-β mono-clonal antibody as an mark tracer.	Same

Analytical Sensitivity	25mIU/mL	25mIU/mL
Specificity	LH at 500 mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 µIU/mL	Same
pH Interference	No interference for urine with pH 3-9	Same
Specific Gravity Interference	No interference for urine with Specific Gravity 1.000-1.035	No interference for urine with Specific Gravity 1.001-1.039
High Dosage Hook effect	No high dosage hook effect for hCG up to 1,000,000 mIU/mL	No high dosage hook effect for hCG up to 850,000 mIU/mL

H. Standards/Guidance Documents Referenced

Guidance for Over-the Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s

I. Test Principle

The HCG Home Use Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The assay is conducted by filling the urine specimen to sample well and observing the formation of red-colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-HCG-colored conjugate and form a red colored line at the test line region of the membrane. The absence of this red colored line suggests a negative result. To serve as a procedural control, a red colored line will always appear in the control line region if the test has been performed properly.

J. Performance Characteristics

1. Analytical performance

a) Precision/Reproducibility

a.1) Sensitivity, Intra-batch precision, Inter-batch precision
A pooled negative female urine was spiked with hCG (traceable to WHO 5th IS） to provide six urine standards with the hCG concentrations of 0,12.5,18.75,25,50,100mIU/ml. using 3 lots of each format of the candidate device were tested by different operator. The samples were blinded and randomized. The sensitivity is 25 mIU/mL hCG. The results are summarized in the tables below:

Table a-1-1: The results of HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

HCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	20	0	20	0	20	0	60	0	100
12.5	0	20	0	20	0	20	0	60	0	100
18.75	8	12	9	11	8	12	25	35	41.67	58.33
25	20	0	20	0	20	0	60	0	100	0
50	20	0	20	0	20	0	60	0	100	0
100	20	0	20	0	20	0	60	0	100	0

Table a-1-2: The results of HCG Home Use Pregnancy Test Strip (Colloidal Gold)

HCG concentration (mIU/mL)	Lot 4		Lot 5		Lot 6		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	20	0	20	0	20	0	60	0	100
12.5	0	20	0	20	0	20	0	60	0	100
18.75	9	11	8	12	8	12	25	35	41.67	58.33
25	20	0	20	0	20	0	60	0	100	0
50	20	0	20	0	20	0	60	0	100	0
100	20	0	20	0	20	0	60	0	100	0

Table a-1-3: The Results of HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

HCG concentration (mIU/mL)	Lot 7		Lot 8		Lot 9		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	20	0	20	0	20	0	60	0	100
12.5	0	20	0	20	0	20	0	60	0	100
18.75	9	11	8	12	8	12	25	35	41.67	58.33
25	20	0	20	0	20	0	60	0	100	0
50	20	0	20	0	20	0	60	0	100	0
100	20	0	20	0	20	0	60	0	100	0

a.2) Inter-day Precision and Inter-round Precision

A pooled negative female urine was spiked with hCG (traceable to WHO 5th IS） to provide six urine standards with the hCG concentrations of 0,12.5,18.75,25,50,100mIU/ml. Over a period of 5 days, with 2 run of testing each day, three operators tested the blinded and randomized samples using 3 lots of each format of candidate device.

Table a-2-1:The Results of HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

HCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	200	0	200	0	200	0	600	0	100
12.5	0	200	0	200	0	200	0	600	0	100
18.75	85	115	89	111	86	114	260	340	43.33	56.67
25	200	0	200	0	200	0	600	0	100	0
50	200	0	200	0	200	0	600	0	100	0
100	200	0	200	0	200	0	600	0	100	0

Table a-2-2:The Results of HCG Home Use Pregnancy Test Strip (Colloidal Gold)

HCG concentration (mIU/mL)	Lot 4		Lot 5		Lot 6		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	200	0	200	0	200	0	600	0	100
12.5	0	200	0	200	0	200	0	600	0	100
18.75	87	113	87	113	88	112	262	338	43.67	56.33

25	200	0	200	0	200	0	600	0	100	0
50	200	0	200	0	200	0	600	0	100	0
100	200	0	200	0	200	0	600	0	100	0

Table a-2-3:The Results of HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

HCG concentration (mIU/mL)	Lot 7		Lot 8		Lot 9		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	200	0	200	0	200	0	600	0	100
12.5	0	200	0	200	0	200	0	600	0	100
18.75	82	118	87	113	86	114	255	345	42.5	57.5
25	200	0	200	0	200	0	600	0	100	0
50	200	0	200	0	200	0	600	0	100	0
100	200	0	200	0	200	0	600	0	100	0

a.3) Inter-laboratory precision

A pooled negative female urine was spiked with hCG (traceable to WHO 5th IS） to provide six urine standards with the hCG concentrations of 0,12.5,18.75,25, 50, 100mIU/ml. The tests were performed on 3 sites using three lots of each format of candidate device. The samples were blinded and randomized.

Table a-3-1:The Results of HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

HCG concentration (mIU/mL)	Site 1 (Lot 1, Lot 2, Lot3)		Site 2 (Lot 1, Lot 2, Lot3)		Site 3 (Lot 1, Lot 2, Lot3)		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	300	0	300	0	300	0	900	0%	100%
12.5	0	300	0	300	0	300	0	900	0%	100%
18.75	150	150	150	150	150	150	450	450	50%	50%
25	300	0	300	0	300	0	900	0	100%	0%
50	300	0	300	0	300	0	900	0	100%	0%
100	300	0	300	0	300	0	900	0	100%	0%

Table a-3-2:The Results of HCG Home Use Pregnancy Test Strip (Colloidal Gold)

HCG concentration (mIU/mL)	Site 1 (Lot 4, Lot 5, Lot 6)		Site 2 (Lot 4, Lot 5, Lot 6)		Site 3 (Lot 4, Lot 5, Lot 6)		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	300	0	300	0	300	0	900	0%	100%
12.5	0	300	0	300	0	300	0	900	0%	100%
18.75	150	150	150	150	140	160	440	460	48.89%	51.11%

25	300	0	300	0	300	0	900	0	100%	0%
50	300	0	300	0	300	0	900	0	100%	0%
100	300	0	300	0	300	0	900	0	100%	0%

Table a-3-3:The Results of HCG Home Use Pregnancy Test Midstream (Colloidal Gold)

HCG concentration (mIU/mL)	Site 1 (Lot 7, Lot 8, Lot 9)		Site 2 (Lot 7, Lot 8, Lot 9)		Site 3 (Lot 7, Lot 8, Lot 9)		Total result		Positive (%)	Negative (%)
	+	-	+	-	+	-	+	-		
0	0	300	0	300	0	300	0	900	0%	100%
12.5	0	300	0	300	0	300	0	900	0%	100%
18.75	130	170	150	150	140	160	420	480	46.67%	53.53%
25	300	0	300	0	300	0	900	0	100%	0%
50	300	0	300	0	300	0	900	0	100%	0%
100	300	0	300	0	300	0	900	0	100%	0%

b) Linearity/Assay Reportable Range

Linearity is not applicable since this is a qualitative test.

c) Traceability

The tests are calibrated against the WHO 5th International Standards for hCG.

d) Stability

A shelf-life stability test of the devices was performed in real-time and accelerated testing. The results showed that the devices were stable for 36 months when stored at 4~30℃ in the sealed foil pouch.

e) Detection Limits (Sensitivity)

Precision section above. According to the results of precision data above, the sensitivity of HCG Urine Test is 25mlU/ml.

f) Analytical Specificity

f.1) Cross reactivity:

Negative and positive female urine contain 12.5mIU/mL and 25 mIU/ml hCG were spiked with various concentrations of the following potential cross reactants: hLH, hFSH, and hTSH. The samples were tested using 3 lots of the test kits. No cross reactivity was observed on the HCG Pregnancy Test

Strip/cassette/
midstream at the concentrations tested below:

Reactant	Concentration at which no significant interference was observed
Human luteinizing hormone (hLH)	500 mIU/mL
Human follicle stimulating hormone (hFSH)	1000 mIU/mL
Human thyrotropin (hTSH)	1 mIU/mL

f.2) Interference:

To evaluate the potential interference of certain exogenous compounds, dilute each interfering substance to the required concentration and add interfering substances to female urine samples containing 0mIU/mL, 10mIU/mL and 25mIU/mL hCG to obtain the required detection samples. Three batches of each format were tested.
The results show that no interferences were observed from substance at the following concentrations for both negative and positive HCG urine samples.

Interfering Substance	**Concentration at which no significant interference was observed**
Glucose	2000mg/dL
Protein	5.65mmol/L
Albumin	2000mg/dL
Bilirubin	2mg/ml
Hemoglobin	1000mg/dL
Caffeine	20mg/dL
Ascorbic acid (Vitamin C)	20mg/dL
Acetaminophen	20mg/mL
Aspirin	20mg/dL
Tetracycline	20mg/dL
Ampicillin	20mg/dL
Erythrocytes	>250/μL
Leukocyte	>500/μl
Uric acid	450mmol/L
Ketone	>80mg/dL
Ethanol	1%
Folic acid	800μg/mL
Vitamin B1	800μg/mL
β-hydroxybutyrate	2000mg/dL
EDTA	80mg/dL
Thiophene	20mg/dL
Benzoylecgonine	10mg/dL
Cannabinol	10mg/dL
Ephedrine	20mg/dL
Phenylpropanolamine	20mg/dL
Phenothiazine	20mg/dL

Effect of urine pH:

Effect of urine pH was performed by adjusting urine samples containing 0mIU/mL, 10mIU/mL and 25mIU/mL hCG urine standard to a pH range of 3.0, 3.5,4.0,4.5,5.0,5.5,6.0,6.5,7.0,7.5,8.0, 8.5, and 9.0. The results demonstrated the subject device will continue to return a correct result when tested with a urine sample in the pH range of 3.0 – 9.0.

Effect of Urine Specific Gravity:

To test the effect of specific gravity, urine samples containing 0mIU/mL, 10 mIU/mL and 25 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. Three batches of each format were tested. The results showed the subject device will continue to return a correct result in response to changes in specific gravity within the range from 1.000 - 1.035.

High Dose Hook Effect Study

To evaluate high dose hook effect, 10 hCG-free specimens were spiked with hCG at 5,000, 10,000, 100,000, 500,000, 650,000, 850,000, 950,000 and 1,000,000 mIU/mL and were tested on three lots of devices for each format. The results demonstrated that no hook effect was observed at hCG concentration up to 1,000,000 mIU/mL.

Effect of hCG β-core fragment:

To evaluate the effects of the hCG β-core fragment, normal non-pregnant women urine specimens containing 0mIU/mL,10mIU/mL and 25mIU/mL hCG were spiked with the hCG β-core fragment at concentrations of 125,000pmol/mL, 250,000pmol/mL, 500,000pmol/mL and 1,000,000pmol/mL. Three lots of each format were tested.
The data demonstrated that there is no interference when the hCG β-core fragment was tested at a concentration of 1,000,000 pmol/L.

2. Comparison Study:

a. Method comparison with predicate device

A total of 300 urine samples from females of childbearing age were collected in this clinical trial for parallel testing. Ages of these women ranged from 18 to 48 years.
Samples were collected at various time throughout the day and were

randomized prior to testing. Testing was performed by laboratory professionals at 3 clinical study unit. Results of the professional using the candidate device were compared to results obtained from the predicate device. Summary of results are presented in the tables below:

The results of professional method comparison (Strip)

Candidate device	Predicate device	
	Positive	Negative
Positive	50	0
Negative	0	50
Total	50	50

The results of professional method comparison (Cassette)

Candidate device	Predicate device	
	Positive	Negative
Positive	50	0
Negative	0	50
Total	50	50

The results of professional method comparison (Midstream, in-stream method)

Candidate device	Predicate device	
	Positive	Negative
Positive	50	0
Negative	0	50
Total	50	50

b. Matrix Comparison

Not Applicable. The device is intended for urine sample only.

3.<u>Lay User Study:</u>

300 women's individual pregnancy status was self-tested. Individuals with varying educational and occupational backgrounds were chosen for the study. 100 lay users using test strip, 100 lay users using test cassette, 100 lay users using the test midstream (in-stream method). Each subject tested her own urine sample using the device according to the package insert and the results of their test were compared to results reported by a laboratory professional using the predicate device.
Samples were also randomized prior to testing and specimens were collected throughout the day and tested.
The results are summarized in the table below.

Results of the lay user method comparison for the HCG Home Use Pregnancy Test Strip (Colloidal Gold)

Candidate device		Predicate device - Professional user		Total
		Positive	Negative	
Lay users	Positive	50	0	50
	Negative	0	50	50
Tobal		50	50	100

Results of the lay user method comparison for the HCG Home Use Pregnancy Test Cassette (Colloidal Gold)

Candidate device		Predicate device - Professional user		Total
		Positive	Negative	
Lay users	Positive	50	0	50
	Negative	0	50	50
Tobal		50	50	100

Results of the lay user method comparison for the HCG Home Use Pregnancy Test Midstream (Colloidal Gold) (in-stream method)

Candidate device		Predicate device - Professional user		Total
		Positive	Negative	
Lay users	Positive	50	0	50
	Negative	0	50	50
Tobal		50	50	100

K. Conclusion

Based on the test principle and performance characteristics of the device including precision, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that the subject device is substantially equivalent to the predicate.