December 22, 2017

True Diagnostics, Inc.
c/o Jinjie Hu
Biologics Consulting Group
1555 King Street, Suite 300
Alexandria, VA 22314

Re: K172257
Trade/Device Name: TrueDX hCG Early Result Pregnancy Test (Midstream Format),
TrueDX hCG Early Result Pregnancy Test (Cassette Format),
VeriClear Early Result Pregnancy Test (Midstream Format),
VeriClear Early Result Pregnancy Test (Cassette Format)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI, LCX
Dated: November 7, 2017
Received: November 9, 2017

Dear Jinjie Hu:

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 Part

801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k172257

Device Name
TrueDx™ hCG Early Result Pregnancy Test (Midstream Format)
TrueDx™ hCG Early Result Pregnancy Test (Cassette Format)

Indications for Use *(Describe)*
TrueDx™ hCG Early Result Pregnancy Test (Midstream & Cassette Format) is rapid chromatographic immunoassay for qualitative detection of human chorionic gonadotropin (hCG) in urine, as an in aid in early detection of pregnancy, in some case as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative result:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test against a few days after you missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.

All results should be confirmed by your healthcare provider, especially when making decision about future medical care.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k172257

Device Name
VeriClear™ Early Result Pregnancy Test (Midstream Format)
VeriClear™ Early Result Pregnancy Test (Cassette Format)

Indications for Use *(Describe)*
VeriClear™ Early Result Pregnancy Test (Midstream & Cassette Format) is rapid chromatographic immunoassay for qualitative detection of human chorionic gonadotropin (hCG) in urine, as an in aid in early detection of pregnancy, in some case as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative result:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test against a few days after you missed period.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.

All results should be confirmed by your healthcare provider, especially when making decision about future medical care.

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)

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K172257 510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with 21CFR807.92.

Date of Summary Prepared: December 20, 2017

Company Name and Address:

True Diagnostics, Inc.
2782 Loker Ave. West
Carlsbad, CA 92010
Tel: (888) 571-8597

Contact Information:

Jinjie Hu Ph.D.
1555 King Street Suite 300
Alexandria, VA 22314
Tel: 301-814-4985
Email: jhu@biologicsconsulting.com

A. 510(k) Number Under Review:
k172257

B. Purpose for Submission:
New Device

C. Measure:
Human Chorionic Gonadotropin (hCG)

D. Type of Test
Qualitative chromatographic immunoassay

E. Applicant:
True Diagnostics, Inc. U.S.A

F. Proprietary and Established Names:

TrueDX™ hCG Early Result Pregnancy Test (Cassette Format)

TrueDX™ hCG Early Result Pregnancy Test (Midstream Format)

VeriClear™ Early Result Pregnancy Test (Cassette Format)

VeriClear™ Early Result Pregnancy Test (Midstream Format)

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1155 Human chorionic gonadotropin (hCG) test System

2. Classification:
   Class II

3. Product Code:
   JHI: Visual Pregnancy, hCG, Prescription
   LCX: hCG, Over the Counter

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for use below

2. Indication(s) for use:

   TrueDX™ hCG Early Result Pregnancy Test (Cassette and Midstream format) is a rapid chromatographic immunoassay for qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

   Important note regarding negative result:
   Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test against a few a few days after you missed period.

   Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.

All results should be confirmed by your healthcare provider, especially when making decision about future medical care.

This product is intended for prescription use.

VeriClear™ Early Result Pregnancy Test (Cassette and Midstream format) is a rapid chromatographic immunoassay for qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative result:

Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should test against a few a few days after you missed period.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. If you test positive, but think you may not be pregnant, you should check with your doctor.

All results should be confirmed by your healthcare provider, especially when making decision about future medical care.

This product is intended for over-the-counter use.

3. Special condition for use statement(s):

   TrueDX™ hCG Early Result Pregnancy Test (Cassette and Midstream format) is intended for prescription use.

   VeriClear™ Early Result Pregnancy Test (Cassette and Midstream format) is intended for over-the-counter use.

4. Special instrument Requirements:

None

I. Device Description:

TrueDX™ hCG Early Result Pregnancy Test is designed to be tested in midstream and cassette mode. Each of the devices (Cassette and Midstream), contains a pouch with the test and instructions for use. The cassette and midstream nitrocellulose test strips are contained in a plastic housing. The cassette test also contains a dropper.

TrueDX™ hCG Early Result Pregnancy Test is a qualitative lateral flow immunoassay for the detection of hCG. The device comes in two formats: Cassette and Midstream. Each device includes a pouch with the all components to perform the test, instruction for use and a desiccant package to control the moisture during the storage of the test kit. The cassette and midstream nitrocellulose test strips are mounted in a plastic housing. The cassette test, which is designed to be used as prescription use contains a dropper pipette.

The VeriClear™ Early Result Pregnancy Test and TrueDX™ hCG Early Result Pregnancy Test are the same devices, except the device names and intended use population.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Church & Dwight Co., FIRST RESPONSE Early Result Pregnancy Test

2. Predicate K number(s):

   K123436

3. Comparison with predicate

Feature	**Proposed Device** K172257	**Predicate Device** K123436
Similarity		
Intended Use	As an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.	Same
Sample Matrix	Urine	Same
Test Principle	Lateral flow sandwich immunochromatographic assay	Same
Limit of Detection	10 mIU/ml	Same
Traceability	WHO 4th International Standard	Same
Time to result	3 minutes	Same
Differences		
Target Users	TrueDX^{TM} hCG Early Result Pregnancy Test (Cassette and Midstream format) is intended for prescription use. VeriClear^{TM} Early Result Pregnancy Test (Cassette and Midstream format) is intended for over the counter use.	Over-the-Counter Use only
Shelf life	24-month shelf life when stored in a dry place between 39 to 86^{o}F	24-month shelf life when stored in a dry place below 86^{o}F
hCG isoforms detected	Intact hCG Hyperglycosylated hCG hCG β -subunit	Intact hCG Hyperglycosylated hCG hCG β -subunit hCG β -core fragment

K. Standard/Guidance Document referenced (if applicable):

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

FDA Guidance document: Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)

L. Test Principle:

TrueDX™ hCG Early Result Pregnancy Test and VeriClear™ Early Result Pregnancy Test are sandwich immunoassays employing mouse monoclonal antibodies specific for hCG, which are immobilized on the membrane as test line, with Goat anti-mouse IgG immobilized as control line. After the urine specimen applied to the device, the analyte hCG present in the specimen will react with the mouse anti hCG monoclonal antibody-colloidal gold conjugate. The complex moves via toward to the testing and control zones. Two lines (both Test and Control) showed on test window 3 minutes after the urine application if hCG is present indicating pregnancy. If Test line is absent and only Control line showed color on the test window after 3 minutes indicating the test works but no hCG present in the specimen. In case the Control line does not show any color 3 minutes after application of the specimen, the test is invalid and the specimen should be retest.

M. Performance Characteristics (if/when applicable):

VeriClear™ Early Result Pregnancy Test and TrueDX™ hCG Early Result Pregnancy Test are identical. Therefore, only one set of representative performance data is presented below.

1. **Analytical performance:**

   a. *Precision/Reproducibility:*
   A precision study was performed using standard samples spiked with hCG traceable to the 4th WHO international standard with hCG concentrations of 0, 3.0 5.0, 8.5, 10, 25, 50, and 100 mIU/ml. Each sample were tested for 10 replicates each day, with three lots of devices (for both formats) by 5 operators, over 5 days. A total of 250 replicates (10 replicates/run x 5 operators x 5 days) per lot device for each sample were obtained.

Precision Study for three lots Devices-Midstream Format

hCG level(mIU/ml)	**Lot 1**	**Lot 2**	**Lot3**	**% Positive**
0	0/250	0/250	0/250	0 %

3	0/250	0/250	0/250	0 %
5	0/250	0/250	0/250	0 %
8.5	135/250	139/250	130/250	53.8 %
10	250/250	250/250	250/250	100%
25	250/250	250/250	250/250	100%
50	250/250	250/250	250/250	100%
100	250/250	250/250	250/250	100%

Precision Study for three lots devices -Cassette Format

hCG level(mIU/ml)	**Lot 1**	**Lot 2**	**Lot3**	**% Positive**
0	0/250	0/250	0/250	0 %
3	0/250	0/250	0/250	0 %
5	0/250	0/250	0/250	0 %
8.5	115/250	110/250	135/250	48 %
10	250/250	250/250	250/250	100%
25	250/250	250/250	250/250	100%
50	250/250	250/250	250/250	100%
100	250/250	250/250	250/250	100%

Precision Study for five Operators -Midstream

hCG level (mIU/ml)	**Operator 1**	**Operator 2**	**Operator 3**	**Operator 4**	**Operator 5**	**% Positive**
0	0/150	0/150	0/150	0/150	0/150	0 %
3	0/150	0/150	0/150	0/150	0/150	0 %
5	0/150	0/150	0/150	0/150	0/150	0 %
8.5	84/150	82/150	79/150	74/150	85/150	53.8%
10	150/150	150/150	150/150	150/150	150/150	100%
25	150/150	150/150	150/150	150/150	150/150	100%
50	150/150	150/150	150/150	150/150	150/150	100%
100	150/150	150/150	150/150	150/150	150/150	100%

Precision Study for five Operators -Cassette

hCG level (mIU/ml)	**Operator 1**	**Operator 2**	**Operator 3**	**Operator 4**	**Operator 5**	**% Positive**

0	0/150	0/150	0/150	0/150	0/150	0 %
3	0/150	0/150	0/150	0/150	0/150	0 %
5	0/150	0/150	0/150	0/150	0/150	0 %
8.5	69/150	69/150	71/150	77/150	74/150	48%
10	150/150	150/150	150/150	150/150	150/150	100%
25	150/150	150/150	150/150	150/150	150/150	100%
50	150/150	150/150	150/150	150/150	150/150	100%
100	150/150	150/150	150/150	150/150	150/150	100%

Within Lot Reproducibility

The repeatability and reproducibility of the TrueDX™ hCG Early Result Pregnancy test (Midstream and cassette format) was challenged over one day with one lot of test device by one operator. This consists of (20) replicates for each level of standard of 0, 3.0 5.0, 8.5, 10, 25, 50, and 100 mIU/ml.

The data has demonstrated excellent within lot repeatability of TrueDX™ hCG Early Result Pregnancy Test. The Results are summarized in the following tables:

Within-Lot Reproducibility

hCG level (mIU/ml)	**Total # of Test**	**TrueDX™ hCG Early Result Pregnancy Test Device Lot#: 0500116 (Simulate Stream Method)**		
		Observed		**% of Positive**
		Negative	**Positive**	
0	20	20	0	100
3.0	20	20	0	100
5.0	20	20	0	100
8.5	20	9	11	55
10.0	20	0	20	100
25.0	20	0	20	100
50.0	20	0	20	100
100.0	20	0	20	100

hCG level (mIU/ml)	**Total # of Test**	**TrueDX™ hCG Early Result Pregnancy Test Device Lot#: 0500116 (Midstream Dip Method)**	
		Observed	**% of Positive**

		Negative	Positive	
0	20	20	0	100
3.0	20	20	0	100
5.0	20	20	0	100
8.5	20	9	11	55
10.0	20	0	20	100
25.0	20	0	20	100
50.0	20	0	20	100
100.0	20	0	20	100

hCG level (mIU/ml)	**Total # of Test**	**TrueDX™ hCG Early Result Pregnancy Test Device (Cassette) Lot #:0501016**		
		Observed		**% of Positive**
		Negative	**Positive**	
0	20	20	0	100
3.0	20	20	0	100
5.0	20	20	0	100
8.5	20	12	8	55
10.0	20	0	20	100
25.0	20	0	20	100
50.0	20	0	20	100
100.0	20	0	20	100

b. *Linearity/assay reportable range:*
Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or method):
Traceability:
The tests are calibrated against the WHO 4thInternational Standards for hCG.

d. Shelf Life
The stability testing protocol and acceptance criteria used to support the shelf life were reviewed and found to be acceptable. The sponsor claims a 24 month shelf life for all two formats when stored in the sealed foil pouch at 39-86ºF (4-30ºC).

e. Detection limits (sensitivity):

An analytical sensitivity study was performed using negative human urine sample spiked with hCG traceable to the WHO 4th IS for hCG to obtain concentration of 0, 3.0, 5.0, 7.5, 8.5, 9.0,10, 12.5, 15, and 25 mIU/ml hCG. The samples were measured in 15 replicates, using 3 different lots of each test format. The tests were performed by 3 different operators for 3 consecutive days. A different set of operators tested each format of the device.

The obtained results are summarized in the following tables.

Midstream Format

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3	% Positive
0	0+/15	0+/15	0+/15	0 %
3	0/+15	0/+15	0/+15	0%
5	0+/15	0+/15	0+/15	0 %
7.5	3+/15	2+/15	3+/15	17.7 %
8.5	8+/15	9+/15	9+/15	57.7%
9.0	14+/15	14+/15	14+/15	93.3 %
10	15+/15	15+/15	15+/15	100 %
12.5	15+/15	15+/15	15+/15	100 %
15	15+/15	15+/15	15+/15	100 %
25	15+/15	15+/15	15+/15	100 %

Cassette Format

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3	% Positive
0	0+/15	0+/15	0+/15	0 %
3	0/+15	0/+15	0/+15	0%
5	0+/15	0+/15	0+/15	0 %
7.5	3+/15	2+/15	4+/15	20%
8.5	8+/15	9+/15	8+/15	55 %
9.0	13+/15	14+/15	13+/15	88.8%
10	15+/15	15+/15	15+/15	100 %
12.5	15+/15	15+/15	15+/15	100 %
15	15+/15	15+/15	15+/15	100 %
25	15+/15	15+/15	15+/15	100 %

The results demonstrated that the analytical sensitivity of the new device (the lowest concentration that yields 100 % positive results) is 10 mIU/ml.

f. Analytical specificity

Structure non-related compounds:

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100 X concentration bulk and spiked into negative urine and positive urine samples (containing 10 mIU /ml hCG). Each spiked urine sample was mixed and to make sure a homogeneous solution before testing. Each sample was tested using 2 different lots of the testing kit. The interference studies demonstrated that there was no interference for the highest concentrations of substance tested for each of the reagent lots and for each concentration of hCG tested negative and 10 mIU/ml hCG).

Analytical Specificity Study

Analytical specificity was studied among potential interfering substances including various prescription and OTC drugs. The name of the substances and the concentration tested listed in the table below. All the substances were tested without hCG or with hCG at 10mIU/ml. All samples were tested in replicates of 5 for each format. No interfering impact was observed on the performance of the candidate test.

Substance tested	**Highest Concentration tested that demonstrated no interference Concentration**
Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Human serum Albumin	2000 mg/dl
Ampicillin	20 mg/dl
Ascorbic acid	20 mg/dl
Atropine	20 mg/dl
Caffeine	20 mg/dl
Cortisol	200 ng/dl
EDTA	80 mg/dL
Phenylpropanolamine	20 mg/dL
Ephedrine	20 mg/dL
Gentisic acid	20 mg/dl
Glucose	2000 mg/dl

Tetracycline	20 mg/dl
Uric acid	10 mg/dl
Bilirubin	20 mg/dL
Ethanol	0.1 %
Salicylic Acid	20 mg/dL

Cross reactivity of structure similar compounds:

Negative and positive urine contain 10 mIU/ml hCG were spiked with various concentrations of the following potential cross reactants: hLH, hFSH, and hTSH. The samples were tested by two operators with two lots of the test kit for each format. The result from spiked samples demonstrated no cross reactivity at following concentrations:

Cross Reactivity Study

TrueDX™ hCG Early Result Pregnancy Test (Midstream format)	
Substance	Concentrations
hLH	1000 mIU/ml
hFSH	1000 mIU/ml
hTSH	1000 µIU/ml

TrueDX™ hCG Early Result Pregnancy Test (Cassette Format)	
Substance	Concentrations
hLH	1000 mIU/ml
hFSH	1000 mIU/ml
hTSH	1000 µIU/ml

Cross reactivity with hyper-glycosylated hCG

A study was performed to evaluate the reactivity of hyper-glycosylated hCG on the device. The h. hCG was made at high concentration bulk and spiked into negative urine. Each spike urine sample (1.47 µg/L, 0.147 µg/L, 0.0147 µg/L and 0.00147 µg/L) was mixed for at least 5 minutes to ensure a homogeneous solution before testing. Each sample was tested using 5 replicates of 3 different lots of each format testing kit. The studies demonstrated that All replicates tested with H. hCG standards at above 0.0147

µg/L (5.8 mIU/ml) yielded positive results with both midstream and cassette format test device.

Effect of urine pH

A study was performed to evaluate the effect of pH on the device. Negative urine and positive urine (10 mIU/ml) were adjusted to have pH values of 4.0, 5.0, 6.0,7.0, 8.0, and 9.0. both negative and positive hCG samples with the different pH levels were tested on each format of device. The positive and negative hCG results were not affected by urine pH levels between the ranges of 4.0 and 9.0.

Effect of urine specific gravity:

A study was performed to evaluate the effect of urine specific gravity on the device. The device was challenged with negative urine and positive urine (containing 10 mIU/ml) with specific gravities of 1.000, 1.005,1.010,1.015,1.020, 1.025,1.030,and 1.035. The positive and negative hCG results were not affected by urine specific gravity concentrations between 1.00 and 1.035

High dose hook effect study:

Negative urine samples were spiked with hCG at concentrations of ranging from 20,000 mIU/ml to 450,000 mIU/ml. Three lots of the device for each format were tested by 2 different operators. The results demonstrated that no hook effect was observed at hCG concentrations up to 450,000 mIU/ml.

Effect of hCG β-core fragment:

Interference testing was performed to evaluate whether high levels of beta core fragment interfere with the test kit. Negative urine hCG (0 mIU/ml and 5 mIU/ml) and positive urine samples (containing 10 mIU/ml,25 mIU/ml and 20,000 mIU/ml) were spiked with hCG beta core fragment at concentrations of 50,400, 102,000, 204,000 and 408,000 p mole/L. Concentration of hCG beta core fragment up to 408,000 p mole/L yielded correct results.

g. *Assay cutoff*

See detection limit section.

The results demonstrated that the analytical sensitivity of the new device (the lowest concentration that yields 100 % of positive results) is 10 mIU/ml.

2. **Comparison studies:**

a. Method comparison with predicate device:

Urine samples were collected from 166 women at physician offices for pregnancy testing. Of the 166 women, 65 of them were suspected to be pregnant. Patient sample were randomly collected at various time throughout the day. Age of these women

ranged from 19 to 41 years. Samples were masked and randomized by people who labeled the sample but did not participate in the testing. A total of 166 samples were tested for each format (Midstream and Cassette). All samples were tested by two different health care professionals. Each person tested two different lots of each format device at same time. For the midstream format, one lot of test device were tested by the simulate stream method, another lot of test device were tested by dip method. The results are summarized in table below.

		Predicate Device		**Total**
		hCG +	**hCG-**	
Candidate Device	**hCG +**	65	0	65
	hCG-	0	101	101
Total		65	101	166

b. Matrix comparison:
Not Applicable

3. **Clinical Studies:**

a. Clinical Sensitivity:
Not Applicable

b. Clinical Specificity:
Not Applicable

c. Other clinical supportive data (when a and b are not applicable):

Detection of hCG in Early Pregnancy Clinical Samples

A total of 616 urine samples urine were collected from 56 different women (25 - 45 years old) who planned to become pregnant. These women were followed throughout their conception cycles with urine collected from day -9 to day +1 of their expected period**.** The Candidate device (both formats) detected hCG in 71% of samples from five days before the expected menstrual period and 100% of samples from one day before the expected menstrual period.

The early pregnancy detection results are summarized below:

Day in cycle relative to EMP	Midstream Format	Cassette Format	Overall Pregnancy Detection Rate (%)
-9 days	0%	0%	0%
-8 days	0%	0%	0%
-7 days	12.5%	12.5%	12.5%
-6 days	41%	41%	41%
-5 days	71%	71%	71%
-4 days	94%	94%	94%
-3 days	98%	98%	98%
-2 days	98%	98%	98%
-1 days	100%	100%	100%
0 days	100%	100%	100%
+1 days	100%	100%	100%

Lay user study

A lay user study was performed at intended use sites with a total of 218 females with diverse educational and professional backgrounds and ages ranging from 18 to 63 years. 110 lay users tested with midstream devices and 108 lay users tested with cassette format devices. Lay users were only provided the package insert prior to perform the study.

Lay user results compare to professional user results are listed below.

Pregnancy Result	Lay user/professional		
	Midstream	Midstream-Dip	Cassette
Pregnant	9/9	9/9	6/6
Non-pregnant	101/101	101/101	102/102
Total	110	110	108

Besides testing their own urine samples, the same lay users also tested spiked urine

samples around the cut-off level at 3.0 mIU, 7.0 mIU/ml, 8.5 mIU/ml and 10 mIU/ml hCG concentrations. A total of 53 samples at each hCG level were tested on Midstream, 57 samples were tested on Midstream using dip method and 110 samples were tested on Cassette format. One lot of each of the two test formats were used in the study. An aliquot of each of the urine samples was also tested by a professional using the candidate device. The results are summarized below.

hCG mIU/ml	Lay user/professional Midstream		Lay user/professional Midstream-Dip method		Lay user/professional Cassette	
	Numbers subject +	Percentage Agreement	Numbers subject +	Percentage Agreement	Numbers subject +	Percentage Agreement
3	0, 0	100%	0, 0	100%	0, 0	100%
7.0	8, 9	98%	20, 18	96%	23, 26	97%
8.5	30, 32	96%	36, 38	96%	81, 84	97%
10	53, 53	100%	57, 57	100%	110, 110	100%

All the lay users participated the study were given a questionnaire to rate how well they understand the instruction in the package insert. A Flesch-kincaid reading analysis was performed to determine that the OTC package insert content is appropriate for a reading Grade level of 7.9. The result of the questionnaire reflect that the consumers found the test easy to use and they did not have trouble understanding the labeling or interpreting results.

Specificity study to determine false-positive result rate

A study was performed to determine the incidence of positive test results from True Diagnostic Early Result Pregnancy Test Device among non pregnant women in three age groups,18 - 41 years of age (Pre-menopausal),42-55 years of age (peri-menopausal) and >55 year of age (post- menopausal). A total of 320 subject provided urine samples with 100 from the pre-menopausal subjects, 111 from the peri-menopausal subjects, and 109 in the post-menopausal subjects. Three lots of each test format of the candidate devices were used for this study. ELISA quantitative analyzed hCG level test kit was used in the study. Subject s with a positive test result on the new device or hCG threshold levels >5.00 MIU/ml on ELISA test procedure were referred to clinical confirmation of positive. The results are summarized in table below:

Age Group	Urine N	Positive result
Pre- Menopausal urines (Age: 18 to 41)	100	0
Peri-menopausal urines (Age: 42 to 55)	111	0
Post-menopausal urines (Age >55)	109	0

4. **Clinical Cut-off**
Not applicable

5. **Expected value/ Reference Range:**
Not applicable

N. Propose Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.