510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k150022

B. Purpose for Submission:

New Device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative chromatographic immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo One Step HCG Urine Pregnancy Test Strip

Wondfo One Step HCG Urine Pregnancy Test Cassette

Wondfo One Step HCG Urine Pregnancy Test Midstream

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 use

LCX: Kit, test, pregnancy, 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:
   Wondfo One Step HCG Urine Pregnancy Test Strip is a rapid chromatographic immunoassay for the 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 results:
   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 again a few days after your 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 decisions about future medical care.

   This product is intended for both prescription use and over-the-counter use.

   Wondfo One Step HCG Urine Pregnancy Test Cassette is a rapid chromatographic immunoassay for the 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 results:
   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 again a few days after your 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 decisions about future medical care.

This product is intended for both prescription use and over-the-counter use.

Wondfo One Step HCG Urine Pregnancy Test Midstream is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.

Important note regarding negative results:
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 again a few days after your 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 decisions about future medical care.

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

3. Special conditions for use statement(s):

   Wondfo One Step HCG Urine Pregnancy Test Strip and Cassette formats are intended for both prescription use and over-the-counter use.

   Wondfo One Step HCG Urine Pregnancy Test Midstream format is intended for over-the-counter use only.

4. Special instrument requirements:

   None

I. Device Description:

The One Step HCG Urine Pregnancy Test is designed to be tested in strip, midstream and cassette mode. Each of the devices (strip, 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

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

2. Predicate 510(k) number(s):

   k123436

3. Comparison with predicate:

Similarities		
Item	Device Wondfo One Step HCG Urine Pregnancy Test	Predicate FIRST RESPONSE Early Result Pregnancy Test (k123436)
Intended Use	Aid in early detection of pregnancy	Same
Early Detection claim	Detects pregnancy as early as 5 days before the expected period or as early as 6 days before the day of the missed period.	Same
Specimen	Urine	Same
Methodology	Immunochromatographic assay	Same
Analytical Sensitivity	10 mIU/mL	Same
Results	Qualitative	Same

Differences		
Item	Device Wondfo One Step HCG Urine Pregnancy Test	Predicate FIRST RESPONSE Early Result Pregnancy Test (k123436)
Intended User	Prescription use (strip and cassette) and OTC use (strip, cassette and midstream)	OTC Use
Device format	Strip, cassette, midstream	Midstream
Time to Result	5 minutes	3 minutes

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

None

L. Test Principle:

The Wondfo One Step HCG Pregnancy Test (Strip, Cassette, Midstream) is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a sample, the sample is absorbed into the device by capillary action and mixes with the antibody-dye conjugate (mouse anti-beta HCG monoclonal antibody), flowing across the pre-coated (Goat anti HCG polyclonal antibody) membrane. During the test, hCG in the urine specimen reacts with the dye conjugate and forms a complex. The complex migrates along the membrane to the α-hCG antibody line (T), and remains captured in the T line. As a result, a red colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. The control line should develop in the Control zone regardless of the result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A precision study was performed using negative human urine samples spiked with hCG traceable to the 4th WHO international standard to obtain samples with hCG concentrations of 0, 2.5, 5, 7.5, 8.0, 10, 15, 20, 25, and 50 mIU/mL. The urine samples were measured in 10 replicates per day using 3 different lots for each device format. Testing was performed for 5 consecutive days by 3 different operators at each of 3 point-of-care sites for a total of 9 operators. A different set of operators tested each format. The results are summarized in the following tables:

Strip Format

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3
0	50-/0+	50-/0+	50-/0+
2.5	50-/0+	50-/0+	50-/0+
5	50-/0+	50-/0+	50-/0+
7.5	36-/14+	35-/15+	36-/14+
8	24-/26+	25-/25+	24-/26+
10	0-/50+	0-/50+	0-/50+
15	0-/50+	0-/50+	0-/50+
20	0-/50+	0-/50+	0-/50+
25	0-/50+	0-/50+	0-/50+
50	0-/50+	0-/50+	0-/50+

Cassette Format

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3
0	50-/0+	50-/0+	50-/0+
2.5	50-/0+	50-/0+	50-/0+
5	50-/0+	50-/0+	50-/0+
7.5	35-/15+	35-/15+	36-/14+
8	25-/25+	24-/26+	24-/26+
10	0-/50+	0-/50+	0-/50+
15	0-/50+	0-/50+	0-/50+
20	0-/50+	0-/50+	0-/50+
25	0-/50+	0-/50+	0-/50+
50	0-/50+	0-/50+	0-/50+

Midstream format

hCG Concentration (mIU/ml)	Lot 1	Lot 2	Lot 3
0	50-/0+	50-/0+	50-/0+
2.5	50-/0+	50-/0+	50-/0+
5	50-/0+	50-/0+	50-/0+
7.5	35-/15+	36-/14+	36-/14+
8	24-/26+	24-/26+	24-/26+
10	0-/50+	0-/50+	0-/50+
15	0-/50+	0-/50+	0-/50+
20	0-/50+	0-/50+	0-/50+
25	0-/50+	0-/50+	0-/50+
50	0-/50+	0-/50+	0-/50+

An additional precision study was conducted to assess the precision of the device at the cut-off concentration of 8 mIU/mL hCG. Ten negative human urine samples were spiked to a concentration of 8 mIU/mL hCG with hCG traceable to the WHO 4th IS for hCG. The samples were tested in replicates of 10 by nine operators who conducted the test with three lots of the device for each format in five consecutive days. The results of the precision study are summarized in the table below:

Precision at the cut-off level of 8 mIU/mL

Format	Lot I	Lot II	Lot III	%Positive
Strip	24-/26+	25-/25+	24-/26+	50.7%
Cassette	25-/25+	24-/26+	24-/26+	50.7%
Midstream	24-/26+	24-/26+	24-/26+	52%

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:
The tests are calibrated against the WHO 4th International Standards for hCG.

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 three test formats when stored in the sealed foil pouch at 39-86^{o} F (4-30^{o} C).

d. *Detection limit:*
An analytical sensitivity/cutoff study was performed using negative human urine samples spiked with hCG traceable to the WHO 4th IS for hCG to obtain concentrations of 0, 5, 7.5, 8, 9,10, 15, 20 mIU /ml hCG. The samples were measured in 10 replicates, two times a day, using 3 different lots of each test format. The tests were performed by twelve different POC operators for 5 consecutive days. A different set of operators tested each format of the device. The obtained results are summarized in the following tables.

Cassette format:

HCG Concentration (mIU/mL)	Lot I	Lot II	Lot III	% Positive
0	20-/0+	20-/0+	20-/0+	0%
5	20-/0+	20-/0+	20-/0+	0%
7.5	14-/6+	14-/6+	15-/5+	28%
8.0	9-/11+	10-/10+	10-/10+	51.7%
9.0	2-/18+	2-/18+	3-/17+	88.3%
10	0-/20+	0-/20+	0-/20+	100%
15	0-/20+	0-/20+	0-/20+	100%
20	0-/20+	0-/20+	0-/20+	100%

Strip format:

HCG Concentration (mIU/mL)	Lot I	Lot II	Lot III	% Positive
0	20-/0+	20-/0+	20-/0+	0%
5	20-/0+	20-/0+	20-/0+	0%
7.5	14-/6+	14-/6+	14-/6+	30%
8.0	10-/10+	10-/10+	10-/10+	50.0%
9.0	2-/18+	2-/18+	3-/17+	88.3%
10	0-/20+	0-/20+	0-/20+	100%
15	0-/20+	0-/20+	0-/20+	100%
20	0-/20+	0-/20+	0-/20+	100%

Midstream format (dip method):

HCG Concentration (mIU/mL)	Lot I	Lot II	Lot III	% Positive
0	20-/0+	20-/0+	20-/0+	0%
5	20-/0+	20-/0+	20-/0+	0%
7.5	14-/6+	14-/6+	14-/6+	30%
8.0	9-/11+	10-/10+	10-/10+	51.7%
9.0	2-/18+	2-/18+	2-/18+	90.0%
10	0-/20+	0-/20+	0-/20+	100%
15	0-/20+	0-/20+	0-/20+	100%
20	0-/20+	0-/20+	0-/20+	100%

Midstream format (simulated stream method)

HCG Concentration (mIU/mL)	Lot I	Lot II	Lot III	% Positive
0	20-/0+	20-/0+	20-/0+	0%
5	20-/0+	20-/0+	20-/0+	0%
7.5	15-/5+	14-/6+	14-/6+	28%
8.0	9-/11+	10-/10+	10-/10+	51.7%
9.0	2-/18+	2-/18+	2-/18+	90.0%
10	0-/20+	0-/20+	0-/20+	100%
15	0-/20+	0-/20+	0-/20+	100%
20	0-/20+	0-/20+	0-/20+	100%

The results demonstrated that the analytical sensitivity of the new device (the lowest concentration that yields 100% positive results) is 10 mIU/mL and the cut-off level (at which approximately half of the devices yield positive results and the remainder

yield negative results) is 8 mIU/mL.

e. *Analytical specificity:*

Interference study
To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked into negative urine and positive urine samples (containing 10 and 100 mIU/mL hCG). Each spiked urine sample was mixed for 5 minutes to ensure a homogeneous solution before testing. Each sample was tested using 3 different lots of the testing kit. The interference studies demonstrated that there was no interference from the highest concentrations of substances tested for each of the three reagent lots and for each concentration of hCG tested (negative, 10, and 100 mIU/mL hCG). The results are summarized in the following table.

Substance Tested	Highest Concentration tested that demonstrated no interference
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	20 mg/dL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
Albumin	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Ephidrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
EDTA	80 mg/dL
Salicyclic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Codeine	6ug/dL
Ethanol	0.1%
Bilirubin	2 mg/dL
Pregnanediol	1500 ug/dL
Thiophene	20 mg/dL
Ketone	20 mg/dL

Cross reactivity of similar compounds:
Negative and positive urine containing10 mIU/mL hCG were spiked with various concentrations of the following potential cross reactants: hLH, hFSH, and hTSH. The samples were tested by three operators with three lots of the strip format device. The results from spiked samples demonstrated no cross reactivity at the following concentrations:

Reactant	Concentration
hLH	500 mIU/mL
hFSH	1000 mIU/mL
hTSH	1000 µIU/mL

Effects of urine pH:
A study was performed to evaluate the effects of pH on the device. Negative urine and positive urine (containing10 and 100 mIU/mL hCG) were adjusted to have pH values of 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0. The negative and positive hCG samples with the different pH levels were tested on each format of the device. The positive and negative hCG results were not affected by urine pH levels between the ranges of 4.0 and 9.0.

Effects of urine specific gravity:
A study was performed to evaluate the effects of urine specific gravity on the device. The device was challenged with negative urine and positive urine (containing10 and 100 mIU/mL hCG) 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 1.000 and 1.035.

High dose hook effect study:
Negative urine samples were spiked with hCG at concentrations of ranging from 6,250 mIU/mL to 200,000 mIU/mL. Three lots of the device were tested by 3 different operators. The results demonstrated that no hook effect was observed at hCG concentrations ranging from 6,250 mIU/mL to 200,000 mIU/mL.

Effects of hCG β-core fragment:
Interference testing was performed to evaluate whether high levels of beta core fragment interfere with the device. Negative urine hCG and positive urine samples (containing 10 mIU/mL hCG) were spiked with hCG beta core fragment at concentrations of 63,000, 125,000 pmol/L, 250,000 pmol/L, and 500,000 pmol/L. Concentrations of hCG beta core fragment up to 250,000 pmol/L yielded correct results. Interference from hCG β-core fragment was demonstrated at concentrations of 500,000 pmol/L.

f. Assay cut-off:

See detection limit section M.1.d.

2. Comparison studies:

   a. *Method comparison with predicate device:*
   Urine samples were collected from 300 women at three different physician's offices for pregnancy testing. Of the 300 women, 146 of them were suspected to be pregnant. Samples were randomly collected at various times throughout the day. Ages of these women ranged from 20 to 45 years. Samples were masked and randomized by people who labeled the samples but did not participate in the testing. A total of 100 samples were tested for each format (strip, cassette, and midstream). All samples were tested by nine different health care professionals at three different physician offices with proposed and the predicate device. Each person tested three different lots of each format device at the same time, but not sequentially. For the midstream format, 50 samples were tested by the dip method and the other 50 samples were tested by simulated stream method. The results are summarized in the tables below:

   Strip Format:

	Predicate device	+	-
Wondfo Device Lots 1,2,3	+	49	0
	-	0	51

   Cassette Format:

	Predicate device	+	-
Wondfo Device Lots 1,2,3	+	48	0
	-	0	52

   Midstream Format:

	Predicate device	+	-
Wondfo Device Lots 1,2,3	+	49	0
	-	0	51

   b. *Matrix comparison:*

   Not applicable. The devices are intended for urine samples only.

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 585 urine samples were collected from 65 different women (21-40 years old) who planned to become pregnant. These women were followed throughout their conception cycles with urine collected from day -8 to day 0 of their expected period. These 585 samples were then tested by laboratory technicians (one for strip, one for cassette format, and two midstream with one each for both dip and stream methods). Urine samples were masked and randomized by people who prepared samples but did not participate in the testing. One lot of each test device was used. The day of the expected period was based on the average number of menstrual cycle days reported for the previous 3 cycles. The pregnancy was confirmed by ultrasound scan. The results are summarized below:

Detection of hCG in Conceptive Cycles Relative to the Day of Expected Menstrual Period (EMP)

Strip format:

Day in cycle relative to EMP	Overall Pregnancy Detection Rate (%)	Number of positive samples	Number of negative samples
-8 days	6 %	4	61
-7 days	14%	9	66
-6 days	38%	25	40
-5 days	68%	44	21
-4 days	89%	58	7
-3 days	97%	63	2
-2 days	98%	64	1
-1 days	100%	65	0
0 days	100%	65	0

Cassette format

Day in cycle relative to EMP	Overall Pregnancy Detection Rate (%)	Number of positive samples	Number of negative samples
-8 days	6 %	4	61
-7 days	14%	9	66
-6 days	38%	25	40
-5 days	68%	44	21
-4 days	89%	58	7
-3 days	97%	63	2
-2 days	98%	64	1
-1 days	100%	65	0
0 days	100%	65	0

Midstream format (dip method)

Day in cycle relative to EMP	Overall Pregnancy Detection Rate (%)	Number of positive samples	Number of negative samples
-8 days	6 %	4	61
-7 days	14%	9	66
-6 days	38%	25	40
-5 days	68%	44	21
-4 days	89%	58	7
-3 days	97%	63	2
-2 days	98%	64	1
-1 days	100%	65	0
0 days	100%	65	0

Midstream format (simulated stream method)

Day in cycle relative to EMP	Overall Pregnancy Detection Rate (%)	Number of positive samples	Number of negative samples
-8 days	6 %	4	61
-7 days	14%	9	66
-6 days	38%	25	40
-5 days	68%	44	21
-4 days	89%	58	7
-3 days	97%	63	2
-2 days	98%	64	1
-1 days	100%	65	0
0 days	100%	65	0

Lay user Study

A lay user study was performed at three intended use sites with a total of 300 females with diverse educational and professional backgrounds and ages ranging from 21 to > 50 years. In this study, 100 lay users tested with the strip devices, 100 lay users tested with the cassette devices and 100 lay users tested with the midstream devices (60 by stream method, 40 by dip method). Of these 300 lay users, 146 of them were suspected to be pregnant. In addition to testing their own urine samples, lay users also tested urine samples at 5.0 and 10mIU/ml hCG concentrations (prepared by spiking hCG into negative pooled urine specimens). The results are summarized below.

Strip Format, lay user urine sample, lay user vs professional:

	Professional	+	-
Lay User	+	49	0
	-	0	51

Strip format, spiked samples tested by lay-users

Number of Samples	hCG Concentration (mIU/mL)	Lay Person Results		Percentage of correct results
		Number of Positive	Number of Negative	
100	5	1	99	99%
100	10	100	0	100%

Cassette Format, lay user urine sample, lay user vs professional

	Professional	+	-
Lay User	+	48	1
	-	0	51

Cassette format, spiked samples tested by lay-users

Number of Samples	hCG Concentration (mIU/mL)	Lay Person Results		Percentage of correct results
		Number of Positive	Number of Negative	
100	5	0	100	100%
100	10	100	0	100%

Midstream Format, lay user urine sample, lay user vs professional

	Professional	+	-
Lay User	+	49	0
	-	0	51

Midstream format, spiked samples tested by lay-users

Number of Samples	hCG Concentration (mIU/mL)	Lay Person Results		Percentage of correct results
		Number of Positive	Number of Negative	
100	5	0	100	100%
100	10	100	0	100%

An additional lay-user study was performed using spiked samples around the cut-off level (7.5 and 8.0 mIU/mL hCG) which were tested by 100 lay-user with diverse educational and professional backgrounds and ages ranging from 20 to 45 years. The testing was performed at 3 intended use sites. One lot of each of the three 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 in the tables below:

Strip format, spiked urine samples, lay user vs professional

No. of samples	hCG Concentration (mIU/mL)	Lay person results		Professionals results		Percent Agreement
		Number of Positive	Number of Negative	Number of Positive	Number of Negative	
100	7.5	26	74	30	70	96%
100	8	49	51	52	48	97%

Cassette format, spiked urine samples, lay user vs professional

No. of samples	hCG Concentration (mIU/mL)	Lay person results		Professionals results		Percent Agreement
		Number of Positive	Number of Negative	Number of Positive	Number of Negative	
100	7.5	25	75	29	71	96
100	8	47	53	51	49	96

Midstream format, spiked urine samples, lay user vs professional

No. of samples	hCG Concentration (mIU/mL)	Lay person results		Professionals results		Percent Agreement
		Number of Positive	Number of Negative	Number of Positive	Number of Negative	
100	7.5	25	75	29	71	96
100	8	49	51	52	48	97

A Flesch-Kincaid reading analysis was performed on each package insert and the score demonstrated a reading Grade Level of 7. The results of the questionnaire reflected that the consumers found the test easy to use and that they did not have trouble understanding the labeling or interpreting results.

Specificity Study to Determine False-Positive Results Rate:

A study was performed to determine the incidence of false positive results in urine from 900 non-pregnant females when tested with the each of the three formats of the candidate device at three different physicians' offices. Urine samples from non-pregnant women in pre-menopausal (18-40 years, n=300), peri-menopausal (41-55 years, n=300), and post-menopausal (>55 years, n=300) age groups were evaluated. Three lots of each test format were used in the study and were randomly distributed among the participants. Non-pregnant females from each age group tested their own urine with each of the test formats based on package insert instructions. The results are summarized in the tables below:

Strip format

Age Group	Lot I	Lot II	Lot III
Pre-menopausal (18 - 40 yrs)	0+/34-	0+/33-	0+/33-
Peri-menopausal	1+/32-	0+/34-	0+/33-

(41-55 yrs)			
Post-menopausal (>55 yrs)	0+/33-	0+/33-	0+/34-

Cassette format

Age Group	Lot I	Lot II	Lot III
Pre-menopausal (18 - 40 yrs)	0+/34-	0+/33-	0+/33-
Peri-menopausal (41-55 yrs)	0+/33-	0+/34-	1+/32-
Post-menopausal (>55 yrs)	0+/33-	0+/33-	0+/34-

Midstream format

Age Group	Lot I	Lot II	Lot III
Pre-menopausal (18 - 40 yrs)	0+/34-	0+/33-	0+/33-
Peri-menopausal (41-55 yrs)	0+/33-	0+/34-	0+/33-
Post-menopausal (>55 yrs)	0+/33-	0+/33-	0+/34-

Combined formats

Age Group	Urine samples (n)	Positive results (%)
Pre-menopausal (18 - 40 yrs)	300	0+/300-
Peri-menopausal (41-55 yrs)	300	2+/298-*
Post-menopausal (>55 yrs)	300	0+/300-

*the two false positive results were obtained by a 49 year old and a 51 year old peri-menopausal women. Quantitative urine testing showed hCG concentrations above threshold levels. Non-pregnancy was confirmed by ultrasound testing.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed 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.