510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

k140893

B. Purpose for Submission:

Clearance of a new instrument and reagent

C. Measurand:

Platelet aggregation

D. Type of Test:

Whole blood platelet aggregation

E. Applicant:

Coramed Technologies, LLC

F. Proprietary and Established Names:

CORA (Coagulation Resonance Analysis) System with Platelet Mapping Assay

G. Regulatory Information:

1. Regulation section:

    21 CFR 864.5700, Automated platelet aggregation system

2. Classification:

    Class II

3. Product code:

    JOZ, System, Automated Platelet Aggregation

4. Panel:

    81 Hematology

H. Intended Use:

1. Intended use(s):

   The CORA PlateletMapping System consists of the CORA (System) analyzer and the CORA PlateletMapping Assay Cartridge. The CORA Platelet Mapping System is intended for *in vitro* diagnostic use to provide qualitative assessment of platelet function. The CORA System records the kinetic changes in a sample of heparinized whole blood as the sample clots.

   The CORA System PlateletMapping Cartridge provides four channels of dried-in-place reagents, HKH (Kaolin with Heparinase), Activator F, AA and ADP (one reagent in each channel). In combination, MA parameter results from these four reagents are used to calculate the parameters platelet % Inhibition and % Aggregation for AA and ADP.

   Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

   The CORA System with PlateletMapping Assay Cartridge is indicated for use with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluation with the CORA PlateletMapping System is used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   Cardiovascular surgery and cardiology procedures (PCI)

4. Special instrument requirements:

   The CORA PlateletMapping Assay Cartridge is for or use with the Coramed CORA (Coagulation Resonance Analysis) analyzer only.

I. Device Description:

The CORA System with PlateletMapping Assay Cartridge consists of a four-channel diagnostic instrument with integrated computer module, system reagents (ActF, AA, ADP, and HKH), and microfluidic test cartridges. See below for a description of system reagents. Reagents are dried-in-place within the cartridges during manufacturing.

The CORA PlateletMapping® Assay Cartridge (for heparinized blood) contain the following reagents:

- HKH (Kaolin with Heparinase), Kaolin + Heparinase
- ActF (ActivatorF)
- ADP (adenosine-5'-diphosphate)
- AA (Arachidonic Acid)

HKH (Kaolin with Heparinase) (for heparinized blood) reagent:
Dried Kaolin, 900 nL spot in reagent chamber of channel, consisting of 33.81% Kaolin (concentration 0.291% w/w) and 66.19% water; dried Heparinase, 900 nL spot in blood well of channel, consisting of 54.52% Heparinase (concentration >1800 IU/mL) and 45.48% water.

ActF (ActivatorF) (for heparinized blood) reagent:
Dried ActivatorF and ReoPro®, 900 nL spot in reagent chamber of channel, consisting of 68.67% ActivatorF and 31.33% ReoPro (Abciximab, 10 mg/5mL vial).

ADP (adenosine-5'-diphosphate) (for heparinized blood) reagent:
Dried ADP and ActivatorF, 900 nL spot in reagent chamber of channel, consisting of 31.33% ADP (concentration 897.38 μM) and 68.67% ActivatorF.

AA (Arachidonic Acid) (for heparinized blood) reagent:
Dried AA and ActivatorF, 900 nL spot in reagent chamber of channel, consisting of 31.33% AA (concentration 60.569 mM) and 68.67% ActivatorF.

J. Substantial Equivalence Information:

1. Predicate device name(s):

    Haemonetics Thromboelastograph® (TEG®) Hemostasis Analyzer with TEG® Platelet Mapping Assay

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

    k041502

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The CORA PlateletMapping System consists of the CORA analyzer and the CORA PlateletMapping Assay.	The TEG® Platelet Mapping Assay is intended to assess platelet function in patients who

Similarities		
Item	Device	Predicate
	The CORA Platelet Mapping System is intended for *in vitro* diagnostic use to provide qualitative assessment of platelet function. The CORA System records the kinetic changes in a sample of heparinized whole blood as the sample clots. The CORA System PlateletMapping Cartridge provides four channels of dried-in-place reagents, HKH (Kaolin with Heparinase), Activator F, AA and ADP (one reagent in each channel). In combination, MA parameter results from these four reagents are used to calculate the parameters platelet % Inhibition and % Aggregation for AA and ADP. Results from the CORA analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The CORA System with CORA PlateletMapping Assay Cartridge is indicated for use with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluation with the CORA PlateletMapping System is used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions.	have received platelet inhibiting drugs. The TEG Hemostasis System is a non-invasive diagnostic instrument designed to monitor and analyze the coagulation state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG analyzer is indicated for use with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.
Matrix	Heparinized whole blood	Same
Measurand	Platelet aggregation	Same
Reagents	Adenosine diphosphate (ADP) Arachidonic acid (AA) Activator F (ActF) Kaolin with Heparinase (HKH)	Same
Output Parameters	MA, % MA reduction	MA, % MA reduction

Differences		
Item	Device	Predicate
Operating Principle	Non-contact measurement of shear elasticity of a coagulating sample: Clotting process causes an increase	Direct-contact measurement of shear elasticity of a coagulating sample:

Differences		
Item	Device	Predicate
	in the modulus of elasticity, which increases stiffness and increases the force of the clot within the ring walls when moving up and down in the ring tube against the sample's own weight. This increases the resonant frequency, which increases the CORA clot strength amplitude.	Clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force binding the cup and pin when the cup rotates. This increases the rotation of the pin, causing increased angular force on the torsion wire, which increases the TEG clot strength amplitude.
Signal Transduction	Optical detection (silicon photodiode) of the motion of a free surface of the sample	Electromechanical detection (rotary variable inductive transformer) of rotary motion of a pin suspended in the sample
Testing Configuration	Vertically-oriented cylindrical container (ring or tube) containing sample with meniscus formed at bottom; non-contact measurement of meniscus amplitude of vibration	Rotating cylindrical container (cup) with pin suspended inside cup; non-contact measurement of pin rotation
Channels	4	2
Temperature Control	20-50ºC	20-40ºC
Total Reaction Volume/channel	20 µL	360-380 µL
Sample Preparation	Performed under instrument control within the disposable cartridge	Performed by the operator using pipettes to reconstitute reagents and mix reagents with the sample
Quality Control	Normal and abnormal donor sample	Level I and Level II coagulation control

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

CLSI EP05-A2, Vol.19, No. 2 *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline*

CLSI EP07-A2, *Interference Testing in Clinical Chemistry; Approved Guideline*

CLSI EP09-A3, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*

CLSI EP25-A, *Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline*

CLSI C28-A3c, *How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline*

IEC 61010-1 *Safety Requirements for Electrical Laboratory Equipment-Part 1: Edition 2*

IEC 61010-1-2:2007 Ed 3: *Medical Electrical Equipment Part 1-2: Electromagnetic Compatibility-Requirements and Tests*

L. Test Principle:

The CORA PlateletMapping Assay is an *in vitro* diagnostic assay used in conjunction with the CORA System (analyzer). This assay specifically determines the Maximum Amplitude (MA), a measure of the maximum firmness of the clot during the test. The assay uses Arachidonic Acid (AA) and/or Adenosine diphosphate (ADP) agonists. Since thrombin (present in blood samples) is the primary and most potent activator of platelets, its activity must be inhibited with heparin in order to assess the platelet inhibiting effects of ADP and AA. Thrombin also converts fibrinogen into fibrin to create the fibrin mesh necessary for any clot formation, and converts Factor XIII to Factor XIIIa for fibrin cross linking.
Since thrombin has been rendered inactive by heparin, Activator F (ActF) is used to replace thrombin's role in the conversion of fibrinogen to fibrin and Factor XIII to Factor XIIIa. Thus, with this cross-linked fibrin network as the foundation (represented by MA_{ActF}), additional clot strength due to platelet-fibrin bonding related to ADP (MA_{ADP}) and AA (MA_{AA}) platelet receptor activation can be measured.
The Kaolin with Heparinase (HKH) reagent, a combination of Kaolin and Heparinase, generates test data for the uninhibited MA (MA_K) resulting from thrombin activation of the blood sample, while the Heparinase neutralizes the effects of heparin.

AA %Aggregation and %Inhibition, and ADP %Aggregation and %Inhibition are parameters derived from the CORA MA parameters for the ActF, AA, ADP and HKH reagents, as described above. Following are the equations used by the CORA System with PlateletMapping Assay Cartridge to derive these parameters:

$$\text{AA Percent Aggregation} = \left[\left\{ \frac{MA_{AA} - MA_{ActF}}{MA_K - MA_{ActF}} \right\} * 100 \right], \quad \text{(maximum of 100\%)}$$

$$\text{ADP Percent Aggregation} = \left[\left\{ \frac{MA_{ADP} - MA_{ActF}}{MA_K - MA_{ActF}} \right\} * 100 \right], \quad \text{(maximum of 100\%)}$$

AA Percent Inhibition = 100 – AA Percent Aggregation, (minimum of 0%)
ADP Percent Inhibition = 100 – ADP Percent Aggregation, (minimum of 0%)

To perform a test, a disposable CORA PlateletMapping Cartridge is inserted into the instrument. Blood is added to an entry port on the cartridge and drawn into the cartridge under instrument control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the blood chambers in the cartridge. Once in the disposable, the sample is metered into as many as four separate analysis channels, depending upon the assay being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

The CORA technology is based on a disposable containing up to four independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube

(ring). Detection of clotting in the CORA System is performed optically. Under control of the instrument, approximately 20μL of prepared sample is delivered to the tube, where a meniscus naturally forms at each end of the tube. The tube is positioned so that the lower meniscus partially blocks light traveling from a collimated source toward a photodiode. During testing, a piezoelectric actuator drives the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The resulting motion of the meniscus is monitored optically and analyzed by the instrument to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Repeatability, Operator-to-Operator Variability, Instrument-to-Instrument Variability were assessed in one combined study. Three different patient samples were tested for HKH Precision testing:
   - Hypocoagulable (donor with coagulation level of MA parameter near the lower limit of the reference range)
   - Normal (donor with coagulation level of MA parameters near the center of the reference range)
   - Hypercoagulable (donor with coagulation level of MA parameter near the upper limit of the reference range)

   For ADP and AA % Aggregation and % Inhibition Precision testing, the following sample types were utilized:
   - Normal [donor with little or no platelet inhibition, inhibition levels below cut-off values (ADP Inhibition <17%, AA Inhibition <11%)]
   - Abnormal (donor with platelet inhibition levels above cut-off values)

   Patient samples were tested in duplicate with each of three reagent lots and six instruments by two operators. Testing was repeated on each of five non-consecutive testing days. A new blood draw from each donor was taken on each of the 5 study days.

   For clarity, the testing schematic for each sample and operator, which was completed on each testing day, is summarized below.

Day	Day 1											
Operator	Operator 1											
Reagent lot	1				2				3			
Instrument	1		2		3		4		5		6	
Replicate	1	2	1	2	1	2	1	2	1	2	1	2

   The analysis of the HKH parameter MA precision performance study is summarized in the table below.

Test	Parameter	Level	n	Mean	Reagent Lot		Operator[1]		Instrument (within Operator, Reagent Lot)		Day (within Instrument, Operator, Reagent Lot)		Repeatability		Total[2]	
					SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
HKH	MA	Hypo	120	59.6	0.35	0.6%	0.22	0.4%	0.00	0.0%	0.96	1.6%	0.39	0.6%	1.12	1.9%
	MA	Hyper	120	67.6	0.11	0.2%	0.07	0.1%	0.00	0.0%	0.56	0.8%	0.46	0.7%	0.74	1.1%
	MA	Normal	120	63.4	0.30	0.5%	0.28	0.4%	0.00	0.0%	0.34	0.5%	0.57	0.9%	0.78	1.2%

[1] Operator includes operator and operator-by-reagent lot interaction

[2] Total includes reagent lot, operator, operator-by-reagent lot interaction, analyzer (within-operator, reagent lot), day (within-instrument, operator, reagent lot) and repeatability

The percent positive and negative agreement for the AA and ADP % aggregation/inhibition at low and high level platelet function samples was 100%.

b. *Assay reportable range:*

The assay reportable range is based on the experimental data provided as part of the method comparison study. If results exceed the reportable range of the assay, results on the display and printed report will be flagged as summarized in the table below:

Reagent	Parameter	Low	High	Within AMR	Below AMR		Above AMR	
				Display & Print	Display	Print	Display	Print
HKH	MA	42	71	Actual value	< 42 !	< 42 !	> 71 !	> 71 !
ActF	MA	2	30	Actual value	< 2 !	< 2 !	> 30 !	> 30 !
ADP	MA	10	72	Actual value	< 10 !	< 10 !	> 72 !	> 72 !
AA	MA	8	76	Actual value	< 8 !	< 8 !	> 76 !	> 76 !

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

Real time and accelerated stability studies were performed in support of a 1-year stability claim for CORA PlateletMapping reagents. Three months of accelerated stability testing was performed with a minimum of two lots of each reagent. The regulatory stability claim is limited to the available real time stability data available at time of clearance.

Real time stability studies included 3 lots of each reagent. At 6 months and 1 year of storage at 2-8 ºC, reagent lots were tested with 2 donor samples in quadruplicate and compared to results generated with one newly manufactured reagent lot. The allowable 10% degradation from the initial value was not exceeded in the indicated testing timeframe, thereby supporting a one year shelf life claim for storage at 2-8 ºC.

In use stability: For each reagent type, two cartridges from each of 3 lots were

removed from their foil pouches at each of multiple time-points and stored at ambient temperature. Cartridges were stored up to 3 hours under in-use conditions prior to testing. Each cartridge was testing with donor blood in quadruplicate. No significant difference in performance was observed after the claimed 2 hours of storage under in-use conditions after removal from the foil pouch.

Transport simulation studies: For each reagent type, 3 lots of reagents were tested for transport stability using a study design based on International Safe Transit Association (ISTA) Procedure 7D "Summer Profile" for 72 hour expedited international airfreight transport. An extended hold at 30 ºC was added to simulate a total of 7 days instead of 3. The study design is summarized in the table below.

1	Temperature Preconditioning	2-8° C for 24 hours
2	Shock - Drop test	Height of drop based on weight of package
3	Temperature Cycle period 1	22° C for 4 hours
4	Vibration	Overall G_{rms} level of 1.15
5	Temperature cycle period 2	35°C for 6 hours
6	Shock - Drop test	Height of drop based on weight of package
7	Temperature cycle period 3	30°C for 152 hours
8	Temperature cycle period 4	35°C for 6 hours

Compared to one lot of reagent stored at the recommended storage conditions of 2-8 ºC, stability of the reagent lots is not impacted by the exposure to the simulated shipping conditions outlined in the table above.

Sample stability: In order to assess sample stability, five consecutive runs of each of three patient samples (normal, hypo and hyper) were tested. Blood samples were tested in quadruplicate at each time point. There is no significant sample deterioration within 2 hours after sample collection.

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Interference studies were carried out according to CLSI EP 7- A2. The effect on hemolysis, hemodilution up to 50% and short draw resulting in up to 2 times heparin concentration were performed for each of the reagents. In addition, the effect of absence of a discard type and addition of EACA on the HKH MA parameter were assessed.

Short draw: For each reagent type, five (5) different samples resulting in final heparin concentrations up to 2 fold were prepared. Each of these samples was tested in quadruplicate. Interference was observed at heparin concentrations equivalent to 2.5mL whole blood in a 4mL heparin containing tube for the ADP and AA reagent.

Hemodilution: Whole blood was hemodiluted up to 50%. Each of the 5 resulting samples was tested in quadruplicate. Hemodilution above 40% was determined to interfere with the HKH and ADP reagent.

Hemolysis: Pooled heparinized blood was split. Half of the blood was hemolyzed *ex vivo*. The effect of lysis on testing results was evaluated by testing each sample 8 times. Hemolysis was found to be an interferent for the HKH and AA reagents.

Lack of discard tube: The effect of discard tube omission on HKH reagent testing was evaluated. In this case, results in the presence and absence of discard tube were compared. For each condition, 8 replicates were tested. No differences in results were observed for the HKH MA parameter.

EACA: The antifibrinolytic substance effect the device output. The effect on adding increasing concentrations of EACA on HKH MA were assessed. Testing was performed in quadruplicate. No interference was observed for EACA concentrations up to 600 µg/mL.

f. *Assay cut-off:*

The assay cut-off was identified utilizing the references range data of healthy patients. The value was identified as the 10% probability quantile for both ADP and AA aggregation. Since inhibition = 100 - aggregation, the inhibition cut-off is based on the 90% probability quantile for AA and ADP Inhibition.

	Cut-off	90% CI Low	90% CI High
ADP Aggregation	83	79	85.8
ADP Inhibition	17	14.2	21
AA Aggregation	89	82.7	93.4
AA Inhibition	11	6.6	17.3

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison studies were conducted at three (3) clinical sites on patient samples following CLSI EP09-A3 Guideline. The subjects enrolled were patients undergoing heart surgery or PCI procedures, with blood samples drawn pre- and post-surgery and in the ICU. Samples were divided and tested with both the CORA PlateletMapping Assay and the Haemonetics TEG® Platelet Mapping Assay. The resulting percent agreement [including positive percent agreement (PPA) and negative percent agreement (NPA)] are summarized below:

	n	Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
ADP Aggregation	261	72 (67-78)	66 (60-73)	90 (82-97)
ADP Inhibition	261	72 (67-78)	90 (82-97)	66 (60-73)
AA Aggregation	267	90(86-94)	91 (87-95)	85 (73-96)
AA Inhibition	267	90 (86-94)	85 (73-96)	91 (87-95)

For the HKH-MA parameter, regression analysis was further performed to compare performance of the CORA PlateletMapping System with the predicate device.

	r	Intercept	95% CI	Slope	95% CI
HKH-MA	0.864	9.412	2.351-16.473	0.866	0.749-0.983

b. *Matrix comparison:*

Not applicable

3. <u>Clinical studies</u>:

a. *Clinical Sensitivity and Specificity:*

Due to the low percentage agreement in the method comparison study, an additional analysis was performed. In this analysis, CORA PlateletMapping assay or the predicate device output was compared to the clinical evaluation of the patients' platelet function status. The presence of normal or abnormal platelet function was determined using the cut-off of <83 for ADP and <89 for AA for the CORA PlateletMapping assay and <80 for the TEG AA and ADP Platelet Mapping assays. Available clinical history (e.g. types of clinical procedures and medications a patient has received) was utilized for the clinical evaluation of the platelet function status (presence or absence of inhibition). The resulting clinical composite was utilized as clinical reference. In all, the results of 203 and 205 patients were included in this analysis for the ADP and AA reagents, respectively.

All sites	ADP		AA	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
CORA	74.5%	72.4%	84.0%	62.5%
95% CI	64.7% - 82.8%	62.8% - 80.7%	77.8% - 89.0%	40.6% - 81.2%
TEG	94.9%	39.0%	88.4%	50.0%
95% CI	88.5% - 98.3%	29.7% - 49.1%	82.8% - 92.7%	29.1% - 70.9%

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

A reader study was performed to determine whether the numerical outputs produced by the CORA PlateletMapping System have the same clinical interpretation as the output produced by the predicate device. In order to do so, a total of 30 paired device

outputs from the CORA PlateletMapping System and the predicate device were provided to 3 readers each at 3 clinical sites, resulting in a total of 270 reads for each parameter.

	n	PA	PPA	NPA
HKH – Hypocoagulable	270	86	61	95
HKH-Hypercoagulable	270	96	84	100
ADP Abnormal	270	80	93	66
AA Abnormal	270	89	91	88

4. Clinical cut-off:

The following cut-offs were utilized in the precision studies and clinical studies in support of the ADP and AA reagents:

	Cut-off
ADP Aggregation	83%
AA Aggregation	89%

Cut-off values were utilized for precision and reader studies for HKH MA parameter. The boundaries of the reference ranges were used to determine whether samples fall into the hypercoagulable, normal or hypocoagulable ranges for the HKH-MA parameter. The following ranges were utilized to select suitable samples for the precision evaluation of the HKH-MA parameter:

	MA Value Range
Hypocoagulable	< 42 - 53
Normal	53 - 68
Hypercoagulable	68 - > 71

5. Expected values/Reference range:

Reference Ranges for each reagent-parameter combination were established in 153 healthy individuals according to CLSI C28-A3c. Samples were excluded on a per-parameter basis using standard outlier criteria. The Minimum and Maximum of the normal range with the respective 95% confidence intervals (95% CI) are summarized in the table below.

	Minimum (95% CI)	Maximum (95% CI)	n
HKH-MA	53 (50-55)	68 (67-72)	149
ActF-MA	2 (2-2)	19 (18-30)	152
ADP-MA	45 (43-50)	69 (67-72)	145
AA-MA	51(49-52)	71(68-77)	144

N. Instrument Name:

CORA® System

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ____x____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___x_____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __x_____ or No _____

3. Specimen Identification:

   The patient ID is entered manually. The reagent cartridge is identified by a bar code on the left side of the cartridge.

4. Specimen Sampling and Handling:

   Heparinized blood is added to the cartridge loaded in the system via a transfer pipette or syringe. Precise measurements are unnecessary but the blood reach an indicator line on the side of the cartridge. The instrument will abort the test if too little blood is present.

5. Calibration:

   Manufacturer calibration

6. Quality Control:

   The CORA analyzer performs internal QC during a pretest to verify the electromechanical and pneumatic functions of the analyzer-cartridge combination are operating satisfactorily. Coramed also recommends that known normal and abnormal donor control checks be performed for each new shipment and lot of PlateletMapping

Assay Cartridges. Additional QC checks may be performed on a monthly, weekly, daily or shift basis based on the laboratory's quality control policies. The end user should follow the recommendations of local and state regulatory agencies as well as facility policies.

P. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Q. Conclusion:

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