510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231752

B Applicant

ARK Diagnostics, Inc.

C Proprietary and Established Names

ARK Hydrocodone Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Hydrocodone

C Type of Test:

Qualitative and semi-quantitative homogeneous immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The ARK Hydrocodone Assay is an immunoassay intended for the qualitative detection and/or semi-quantitative estimation of hydrocodone and its metabolites in human urine at a cutoff of 300 ng/mL. The semi-quantitative mode is for the purpose of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method, such as Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS), or (2) permitting laboratories to establish quality control procedures.

The ARK Hydrocodone Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Beckman Coulter AU 680 chemistry analyzer was used to generate data for this submission.

IV Device/System Characteristics:

A Device Description:

The ARK Hydrocodone Assay is a homogeneous enzyme immunoassay (HEIA) technique used for the analysis of Hydrocodone in human urine. The ARK Hydrocodone Assay test system includes separately provided test kits for the ARK Hydrocodone Assay.

The ARK Hydrocodone Assay consists of reagents R1 and R2.

Reagent R1 – Antibody/Substrate solution contains: Rabbit monoclonal antibodies to hydrocodone, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers.

Reagent R2 – Enzyme solution contains: Hydrocodone derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizer.

B Principle of Operation:

The ARK Hydrocodone Assay is a homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect hydrocodone and its metabolites without any significant cross-

reactivity to other opiate compounds. The assay is based on competition between a drug labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) and free drug from the urine sample, for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, rabbit monoclonal anti-hydrocodone antibody binds to the drug labeled with rG6PDH and causes a decrease in enzyme activity. In the presence of hydrocodone from the specimen, enzyme activity increases and is directly related to the hydrocodone concentration. Endogenous G6PDH does not interfere because the coenzyme NAD functions only with the bacterial enzyme used in the assay. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

V Substantial Equivalence Information:

A Predicate Device Name(s):
DRI Hydrocodone Assay

B Predicate 510(k) Number(s):
K150502

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231752	K150502
Device Trade Name	ARK Hydrocodone Assay	DRI Hydrocodone Assay
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the detection and estimation of hydrocodone in human urine	Same
Assay cutoff	300 ng/mL of Hydrocodone	Same
Test system type	Homogenous enzyme immunoassay	Same
Sample Matrix	Human urine	Same
General Device Characteristic Differences		
Antibody	Rabbit monoclonal	Mouse monoclonal
Calibrator Levels	0, 50, 100, 300, 800 ng/mL	0, 100, 300, 500, 1000 ng/mL

VI Standards/Guidance Documents Referenced:

- CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance.
- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.
- CLSI EP07-A3: Interference Testing in Clinical Chemistry.

- CLSI EP37: Supplemental Tables for Interference Testing in Clinical Chemistry - First Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A precision study was performed based upon recommendations in the CLSI (EP5-A3) guideline. Drug free urine samples were spiked with hydrocodone at 0, 75, 150, 225, 300, 375, 450, 525 and 600 ng/mL, representing 0, 25, 50, 75, 100, 125, 150, 175 and 200% of the device cutoff (300 ng/mL). Each sample was tested in quadruplicate per run, two runs per day for twenty consecutive days (total N= 160/level/reagent lot) using 2 reagent lots on the Beckman Coulter AU680 chemistry analyzer. The results are shown below:

   Qualitative Precision Results:

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Lot 1 Precision Results	Lot 2 Precision Results
0	-100	160	160 Negative	160 Negative
75	-75	160	160 Negative	160 Negative
150	-50	160	160 Negative	160 Negative
225	-25	160	160 Negative	160 Negative
300	Cutoff	160	50 Negative; 110 Positive	69 Negative; 91 Positive
375	+25	160	160 Positive	160 Positive
450	+50	160	160 Positive	160 Positive
525	+75	160	160 Positive	160 Positive
600	+100	160	160 Positive	160 Positive

Semi-Quantitative Precision Results:

Semi-quantitative Precision Lot 1

Human Urine (ng/mL)	Relative % Cutoff	Precision Results	Repeatability (Within-Run Precision)		Between Day Precision		Total Precision (Within-Laboratory Precision)	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
0	-100	160 Negative	1.2	N/A	0.4	N/A	1.2	N/A
75	-75	160 Negative	2.3	3.0	1.8	2.3	3.0	3.9
150	-50	160 Negative	6.3	4.4	4.0	2.8	7.5	5.3
225	-25	160 Negative	7.8	3.4	5.5	2.4	10.1	4.4
300	Cutoff	24 Negative;	11.1	3.5	7.9	2.5	14.7	4.7

Human Urine (ng/mL)	Relative % Cutoff	Precision Results	Repeatability (Within-Run Precision)		Between Day Precision		Total Precision (Within-Laboratory Precision)	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
		136 Positive						
375	+25	160 Positive	14.3	3.7	11.2	2.9	18.8	4.8
450	+50	160 Positive	20.9	4.5	16.5	3.6	27.9	6.1
525	+75	160 Positive	31.7	5.9	24.2	4.5	43.6	8.1
600	+100	160 Positive	50.4	8.1	38.3	6.2	61.4	9.9

Semi-quantitative Precision Lot 2

Human Urine (ng/mL)	Relative % Cutoff	Precision Results	Repeatability (Within-Run Precision)		Between Day Precision		Total Precision (Within-Laboratory Precision)	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
0	-100	160 Negative	1.4	N/A	0.7	N/A	1.6	N/A
75	-75	160 Negative	3.2	4.2	1.8	2.4	3.7	4.9
150	-50	160 Negative	3.3	2.3	2.1	1.4	4.5	3.1
225	-25	160 Negative	6.8	2.9	4.3	1.9	8.1	3.5
300	Cutoff	35 Negative; 125 Positive	10.2	3.3	6.9	2.2	11.7	3.8
375	+25	160 Positive	16.7	4.3	12.0	3.1	20.0	5.2
450	+50	160 Positive	26.3	5.7	11.5	2.5	27.3	5.9
525	+75	160 Positive	34.1	6.5	10.8	2.1	35.0	6.7
600	+100	160 Positive	45.6	7.5	10.1	1.7	45.6	7.5

2. Linearity/Recovery:

Linearity study in the semi-quantitative mode was conducted by spiking a drug free urine pool with hydrocodone (serial dilutions of a high concentration hydrocodone in negative urine pool) to achieve concentrations ranging from 0 ng/mL to 800 ng/mL, and testing each level on two reagent lots in replicates of five on the Beckman Coulter AU680 clinical chemistry analyzer. The results from a representative lot are summarized below:

Expected Value (ng/mL)	Observed Value (ng/mL)	Recovery (%)
0	0.0	N/A
80	79.4	99.3
160	151.1	94.5
240	246.8	102.9
320	321.7	100.5
400	385.8	96.5
480	472.3	98.4
560	537.4	96.0
640	606.4	94.7
720	620.6	86.2
800	737.5	92.2

3. Analytical Specificity/Interference:

Specificity:

An analytical specificity study to evaluate interference from non-structurally and structurally related compounds was performed in the qualitative and semi-quantitative mode. The study design and results are described below. Results were the same for each mode (qualitative and semi-quantitative modes).

Hydrocodone and its Metabolites

The following metabolites of hydrocodone were approximately equivalent to the 300 ng/mL cutoff at the concentrations tested with the ARK Hydrocodone Assay. Dihydrocodeine tested negative at 100,000 ng/mL. Immunoassay reactivity for hydrocodone and hydromorphone were equivalent.

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Hydrocodone	292	102.8
Hydromorphone	299	100.4
Hydromorphone-3β-Glucuronide	45,439	0.7
Norhydrocodone	2,277	13.2
Dihydrocodeine	>100,000	<0.3

Structurally Related Compounds and Other Opiates

To evaluate potential cross-reactivity for the ARK Hydrocodone assay, structurally similar compounds were spiked into drug free urine at concentrations that will yield a result that is equivalent to the 300ng/mL cutoff. For compounds that did not produce a positive result, the

highest concentration tested was used to calculate percent cross-reactivity. The percent cross-reactivity is presented in the table below.

Compound	Concentration Tested (ng/mL)	Result N=3 (POS/NEG)	Percent Cross-reactivity (%)
6-Acetyl morphine	100,000	NEG	<0.3
Buprenorphine	100,000	NEG	<0.3
Buprenorphine-3β-D-glucuronide	50,000	NEG	<0.6
Codeine	100,000	NEG	<0.3
Codeine-6β-D-glucuronide	100,000	NEG	<0.3
Dextromethorphan	250,000	NEG	<0.1
EDDP	100,000	NEG	<0.3
EMDP	100,000	NEG	<0.3
Ethyl morphine	100,000	NEG	<0.3
Fentanyl	100,000	NEG	<0.3
Heroin	100,000	NEG	<0.3
Levorphanol	100,000	NEG	<0.3
Meperidine	100,000	NEG	<0.3
Methadone	100,000	NEG	<0.3
Morphine	100,000	NEG	<0.3
Morphine-3β-D-glucuronide	100,000	NEG	<0.3
Morphine-6β-D-glucuronide	100,000	NEG	<0.3
Nalbuphine	100,000	NEG	<0.3
Naloxegol	100,000	NEG	<0.3
Naloxone	100,000	NEG	<0.3
Naltrexone	100,000	NEG	<0.3
Norbuprenorphine	100,000	NEG	<0.3
Norcodeine	100,000	NEG	<0.3
Normorphine	100,000	NEG	<0.3
Noroxycodone	100,000	NEG	<0.3
Nortilidine	100,000	NEG	<0.3
Oxycodone	100,000	NEG	<0.3
Oxymorphone	100,000	NEG	<0.3
Oxymorphone-3β-D-glucuronide	50,000	NEG	<0.6
Pentazocine	100,000	NEG	<0.3
Tapentadol	100,000	NEG	<0.3
Thebaine	100,000	NEG	<0.3
Tilidine	100,000	NEG	<0.3
Tramadol	100,000	NEG	<0.3

Non-Structurally Related Compounds

Potential interference from non-structurally related drugs and metabolites was evaluated in the qualitative and semi-quantitative modes, by spiking these compounds at high concentrations in drug free urine spiked with hydrocodone at ± 25% of the cutoff (225 and 375 ng/mL).

Compound	Concentration Tested (ng/mL)	Result N=3 (POS/NEG)
(+)-MDA	100,000	NEG
11-hydroxy-delta-9-THC	100,000	NEG
11-nor-9 carboxy THC	50,000	NEG
1R,2S(-)-Ephedrine	100,000	NEG
1S,2R(+)-Ephedrine	100,000	NEG
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	NEG
7-Aminoclonazepam	100,000	NEG
Acetaminophen	500,000	NEG
Acetylsalicylic acid	500,000	NEG
Alprazolam	100,000	NEG
Amitriptyline	100,000	NEG
Amobarbital	100,000	NEG
Amoxicillin	100,000	NEG
Amphetamine	100,000	NEG
Atorvastatin	100,000	NEG
Benzoylecgonine	1,000,000	NEG
Benzylpiperazine	100,000	NEG
Bupropion	100,000	NEG
Butabarbital	100,000	NEG
Caffeine	100,000	NEG
Canagliflozin	50,000	NEG
Cannabidiol	100,000	NEG
Cannabinol	100,000	NEG
Carbamazepine	500,000	NEG
Carisoprodol	100,000	NEG
Chlordiazepoxide	100,000	NEG
Chlorpromazine	100,000	NEG
Cimetidine	500,000	NEG
Clobazam	100,000	NEG
Clomipramine	100,000	NEG
Clopidogrel	100,000	NEG
Cocaine	100,000	NEG
Cotinine	100,000	NEG
Cyclobenzaprine	100,000	NEG
Desipramine	100,000	NEG
Diazepam	100,000	NEG

Compound	Concentration Tested (ng/mL)	Result N=3 (POS/NEG)
Diphenhydramine	100,000	NEG
Doxepin	100,000	NEG
Ecgonine	100,000	NEG
Ephedrine	1,000,000	NEG
Fluoxetine	100,000	NEG
Fluphenazine	100,000	NEG
Ibuprofen	500,000	NEG
Imipramine	100,000	NEG
Ketamine	100,000	NEG
Lamotrigine	100,000	NEG
Lidocaine	100,000	NEG
LSD	100,000	NEG
Maprotiline	100,000	NEG
MDMA	50,000	NEG
Meprobamate	100,000	NEG
Metformin	100,000	NEG
Methylphenidate	250,000	NEG
Metronidazole	100,000	NEG
Naproxen	100,000	NEG
Norpseudoephedrine	50,000	NEG
Nortriptyline	100,000	NEG
Omeprazole	100,000	NEG
Ondansetron	100,000	NEG
Oxazepam	250,000	NEG
Phencyclidine	100,000	NEG
Phenobarbital	100,000	NEG
Phentermine	100,000	NEG
Phenylephrine	100,000	NEG
Phenylpropanolamine	100,000	NEG
Phenytoin	100,000	NEG
PMA	100,000	NEG
Propranolol	100,000	NEG
Protriptyline	100,000	NEG
R,R(-)-Pseudoephedrine	100,000	NEG
Ranitidine	500,000	NEG
Ritalinic Acid	100,000	NEG
S(+)-Methamphetamine	100,000	NEG
S,S(+)-Pseudoephedrine	100,000	NEG
Salicylic Acid	100,000	NEG
Secobarbital	100,000	NEG
Sertraline	100,000	NEG
Temazepam	100,000	NEG

Compound	Concentration Tested (ng/mL)	Result N=3 (POS/NEG)
Theophylline	50,000	NEG
Thioridazine	100,000	NEG
Trazodone	100,000	NEG
Triazolam	250,000	NEG
Trimipramine	100,000	NEG
Venlafaxine	100,000	NEG
Zolpidem	100,000	NEG

Endogenous Compounds

Potential interference from endogenous compounds commonly found in urine was evaluated in the qualitative and semi-quantitative modes, by spiking these compounds into drug free urine containing hydrocodone at ± 25% of the 300 ng/mL cutoff (225 and 375 ng/mL).

Interfering Substances	Concentration Tested (mg/dL)	225 ng/mL Hydrocodone N=3 (POS/NEG)	375 ng/mL Hydrocodone N=3 (POS/NEG)
Acetaminophen	10	NEG	POS
Acetone	500	NEG	POS
Acetyl Salicylic Acid	10	NEG	POS
Ascorbic acid	150	NEG	POS
Caffeine	10	NEG	POS
Creatinine	400	NEG	POS
Ethanol	10	NEG	POS
Galactose	5	NEG	POS
Glucose	1000	NEG	POS
Hemoglobin	150	NEG	POS
Human Serum Albumin	200	NEG	POS
Human γ- Globulin	500	NEG	POS
Ibuprofen	10	NEG	POS
NaCl	1000	NEG	POS
Oxalic Acid	50	NEG	POS
Riboflavin	3	NEG	POS
Urea	1000	NEG	POS

pH and Specific Gravity:

For potential interference from the pH of urine, device performance in the qualitative and semi-quantitative modes was tested using a range of urine pH values (3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0,10.0 and 11.0). All test samples were prepared in drug free urine containing hydrocodone at ± 25% of the cutoff (225 ng/mL and 375 ng/mL hydrocodone

concentrations). No positive or negative interference was observed at urine pH values ranging from 3.0 to 11.0 for each test mode.

For potential interference from the specific gravity of urine, device performance in the qualitative and semi-quantitative modes was tested using a range of urine specific gravity values (1.000, 1.0021, 1.0043, 1.0179, 1.0187, 1.0262, 1.0303). All test samples were prepared in drug free urine containing hydrocodone at ± 25% of the cutoff (225 ng/mL and 375 ng/mL hydrocodone concentrations). No positive or negative interference was observed at urine specific gravity values ranging from 1.000 to 1.0303 for each test mode.

Boric Acid:
One percent (1%) w/v of boric acid was tested in the presence of hydrocodone at 225 ng/mL and 375 ng/mL.

Compound	Concentration Tested	225 ng/mL Hydrocodone N=3 (POS/NEG)	375 ng/mL Hydrocodone N=3 (POS/NEG)
Boric Acid	1% w/v	NEG	NEG

The following limitations statement is included in the Instructions for Use/Package Insert:

"**Do not use Boric Acid as a preservative."**

4. Assay Reportable Range:

   See the linearity section, VII.A.2., above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability: ARK Hydrocodone Assay is traceable to a commercially available standard.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Characterization of how the device performs analytically around the claimed cutoff concentration of 300 ng/mL hydrocodone is described in the precision section, VII.A.1., above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A total of 226 unaltered urine samples from pain management laboratories were analyzed by two lots of the candidate device in the qualitative and semi-quantitative modes on the Beckman Coulter AU680 clinical chemistry analyzer and the comparative mass spectrometry based quantitative method (LC-MS/MS). LC-MS/MS and immunoassay qualitative results are based on a 300ng/mL cutoff. The results from the study in the two modes are summarized below:

Lot 1 Qualitative method comparison with LC-MS/MS as reference method

ARK Hydrocodone Assay Results	<50% of cutoff concentration by LC-MS/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (150-299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (300-450 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS)
Positive	8*	8*	9	66
Negative	134	0	1*	0

Lot 2 Qualitative method comparison with LC-MS/MS as reference method

ARK Hydrocodone Assay Lot 2 Results	<50% of cutoff concentration by LC-MS/MS (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (150-299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (300-450 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>450 ng/mL)
Positive	8*	8*	9	66
Negative	134	0	1*	0

Lot 1 Semi-quantitative method comparison with LC-MS/MS as reference method

ARK Hydrocodone Assay Lot 1 Results	<50% of cutoff concentration by LC-MS/MS (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (150-299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (300-450 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>450 ng/mL)
Positive	8*	8*	9	66
Negative	134	0	1*	0

Lot 2 Semi-quantitative method comparison with LC-MS/MS as reference method

ARK Hydrocodone Assay Lot 2 Results	<50% of cutoff concentration by LC-MS/MS (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (150-299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (300-450 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>450 ng/mL)
Positive	8*	8*	10	66
Negative	134	0	0	0

***Discordant Results**

Sample #	ARK Lot 1 Qual. (POS/ NEG)	ARK Lot 2 Qual. (POS/ NEG)	LC-MS/MS (ng/mL)		ARK Lot 1 Semi-quant. (ng/ mL)	ARK Lot 2 Semi-quant. (ng/ mL)
			Hydrocodone	Hydromorphone		
3	POS	POS	287.8	210.0	476.0	664.3
15	POS	POS	226.9	150.5	390.0	415.0
18	POS	POS	156.0	174.7	335.2	338.6
23	POS	POS	5.4	1317.7	387.7	467.9
38	**NEG**	**NEG**	**306.5**	**22.4**	**277.6**	**307.0**
39	POS	POS	162.0	52.4	316.1	312.8
48	POS	POS	200.5	61.7	358.4	347.9
51	POS	POS	174.4	29.0	357.4	393.0

Sample #	ARK Lot 1 Qual. (POS/ NEG)	ARK Lot 2 Qual. (POS/ NEG)	LC-MS/MS (ng/mL)		ARK Lot 1 Semi-quant. (ng/ mL)	ARK Lot 2 Semi-quant. (ng/ mL)
			Hydrocodone	Hydromorphone		
66	POS	POS	146.7	190.3	463.1	440.5
68	POS	POS	181.2	150.3	382.2	376.7
70	POS	POS	Not Detected	545.7	445.7	480.2
75	POS	POS	5.9	10524.1	2549.1	2922.0
86	POS	POS	255.8	30.7	471.4	412.4
90	POS	POS	106.5	214.0	335.5	333.7
97	POS	POS	Not Detected	1769.8	501.3	483.9
99	POS	POS	Not Detected	706.1	657.9	609.1
101	POS	POS	Not Detected	5461.7	2014.2	2112.0

For Sample #38, the hydrocodone concentration was 306.5 ng/mL by LC-MS/MS and 307.0 ng/mL (positive) in semi-quantitative protocol and negative in the qualitative mode. The remaining 16 discordant samples all tested positive, greater than cutoff, by both ARK assay protocols. Cross-reactivity to the major metabolite hydromorphone contributed to the positive results for some of the samples with <300 ng/mL hydrocodone by LC-MS/MS.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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