ARK Diagnostics, Inc.
Thomas Houts, Ph.D.
Sr. Director, Quality, Regulatory and Planning
48089 Fremont Boulevard
Fremont, California 94538

Re: K231752
Trade/Device Name: ARK Hydrocodone Assay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: October 6, 2023
Received: October 6, 2023

Dear Thomas Houts:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2023.11.09 11:26:43 -05'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231752

Device Name
ARK Hydrocodone Assay

Indications for Use *(Describe)*
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.

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.

Section 05: 510(k) SUMMARY

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is K231752.

807.92 (a)(1): Name: **ARK Diagnostics, Inc.**

Address: 48089 Fremont Blvd
Fremont, CA 94538 USA

Owner Operator Number: 10027663
Establishment Registration: 3005755244

Phone: (510) 270-6270
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Contact: Thomas Houts, Ph.D., FAACC
ARK Diagnostics, Inc.
Director, Quality, Regulatory and Planning
Telephone: (510) 270-6296
E-mail: tom@ark-tdm.com

Date Prepared: June 5, 2023

807.92 (a)(2): Device Name – Trade Name, Common Name, and Classification

Trade Name: ARK Hydrocodone Assay

Common Name: Homogeneous Enzyme Immunoassay, Opiate Test System

Classification:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 Opiate Test System	Toxicology (91)

807.92 (a)(3): Identification of the Legally Marketed Predicate Device

DRI Hydrocodone Assay (K150502)

807.92 (a)(4): Device Description

The ARK Hydrocodone Assay is supplied as a liquid ready-to-use homogeneous enzyme immunoassay. The assay is based on competition between hydrocodone in the specimen and hydrocodone labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) for antibody binding sites. As the latter binds antibody, enzyme activity decreases. In the presence of hydrocodone from the specimen, enzyme activity increases and is directly related to the hydrocodone concentration. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically. Endogenous G6PDH does not interfere because the coenzyme NAD functions only with the bacterial enzyme used in the assay.

The ARK Hydrocodone Assay consists of reagents R1 anti-hydrocodone monoclonal rabbit antibodies with substrate and R2 hydrocodone derivative labeled with bacterial recombinant G6PDH enzyme.

807.92 (a)(5): Intended Use / Indications for Use

ARK Hydrocodone Assay

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.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

SUBSTANTIAL EQUIVALENCE COMPARATIVE TABLE

Comparison between the DRI Hydrocodone Assay and the ARK Hydrocodone Assay

Characteristic	**Predicate Device** DRI Hydrocodone Assay (K150502)	**Candidate Device** ARK Hydrocodone Assay
Similarities		
Test System	Homogenous enzyme immunoassay (HEIA)	Same
Intended Use	The DRI® Hydrocodone Assay is intended for the qualitative and semi-quantitative detection and estimation of Hydrocodone and its metabolites in human urine at a cutoff of 300 ng/mL. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of specimen for confirmation by a confirmatory method such as LC-MS/MS or GCMS and permitting laboratories to establish quality control measures. This assay provides a preliminary analytical test result. A more specific alternative chemical method must be used in order to confirm an analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.	Same
Sample Matrix	Human urine	Same
User Environment	Clinical laboratory; Prescription use only	Same

Mass Spectrometry Confirmation	Required to confirm preliminary positive analytical results	Same
Platform Required	Automated clinical chemistry analyzer	Same
Reagents Form	Liquid – Ready-to-use	Same
Reagent Materials	Two (2) reagent system: Antibody/substrate reagent (mouse monoclonal antibodies to hydrocodone) and enzyme labeled conjugate (hydrocodone derivative labeled with enzyme) Sodium azide preservative	Two (2) reagent system: Antibody/substrate reagent (rabbit monoclonal antibodies to hydrocodone) and enzyme labeled conjugate (hydrocodone derivative labeled with enzyme) Sodium azide preservative
Quality Controls	Two levels – 225 and 375 ng/mL	Same
Storage	2-8˚C until expiration date	Same
Measured Analyte	Hydrocodone	Same
Detection	Absorbance change measured spectrophotometrically at 340 nm	Same
Cutoff Level	300 ng/mL	Same
Control Levels	225 and 375 ng/mL	Same

Characteristic	**Predicate Device** DRI Hydrocodone Assay (K150502)	**Candidate Device** ARK Hydrocodone Assay
Differences		
Antibody	Mouse monoclonal	Rabbit monoclonal
Calibrator Levels	0, 100, 300, 500, 1000 ng/mL	0, 50, 100, 300, 800 ng/mL

807.92 (b)(1) and 807.92 (b)(2): Brief Description of Nonclinical and Clinical Data

The following performance characteristics were obtained on the Beckman Coulter AU680® automated clinical chemistry analyzer.

Precision

Precision studies were performed using CLSI EP05-A3 as a guideline. Drug-free, negative human urine was supplemented with hydrocodone (0 to 600 ng/mL). Each level was assayed in quadruplicate twice a day for 20 days (N=160) and evaluated qualitatively and semi-quantitatively. Results are summarized in the tables below.

Qualitative Precision

Hydrocodone (ng/mL)	Relative % Cutoff	# of Results	Precision Results
0	-100	160	160 Neg
75	-75	160	160 Neg
150	-50	160	160 Neg
225	-25	160	160 Negative
300	Cutoff	160	50 Neg / 110 Pos
375	+25	160	160 Pos
450	+50	160	160 Pos
525	+75	160	160 Pos
600	+100	160	160 Pos

Semi-quantitative Precision

Hydrocodone (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Precision Results
0	-100	160	0	160 Neg
75	-75	160	78	160 Neg
150	-50	160	142	160 Neg
225	-25	160	229	160 Neg
300	Cutoff	160	314	24 Neg / 136 Pos
375	+25	160	388	160 Pos
450	+50	160	459	160 Pos
525	+75	160	539	160 Pos
600	+100	160	620	160 Pos

Analytical Recovery

Drug-free, negative human urine was spiked with hydrocodone across the assay range of the semi-quantitative calibration curve. Each sample was run in replicates of 5 in semi-quantitative mode and the average was used to determine percent recovery compared to the expected value.

Expected Value (ng/mL)	Observed Value (ng/mL)	Recovery (%)
0	0	N/A
80	80	99
160	151	94
240	247	103
320	322	101
400	386	96
480	472	98
560	537	96
640	606	95
720	621	86
800	738	92

Analytical Specificity

All compounds tested were added to drug-free, negative human urine and tested with the ARK Hydrocodone Assay in both qualitative and semi-quantitative modes.

The cross-reactivity of hydrocodone and its metabolites was evaluated by spiking these compounds into drug-free, negative human urine and evaluated by dose-response to determine the approximate equivalence to the 300 ng/mL hydrocodone cutoff. These concentrations were used to determine the percent cross-reactivity according to the formula:

% Cross-reactivity = (Cutoff concentration / Concentration approximately equivalent to the 300 ng/mL cutoff) X 100

For compounds that did not produce a positive result, the highest concentration tested was used to calculate percent cross-reactivity.

Cross-reactivity of hydrocodone and its metabolites

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Cross-reactivity (%)
Hydrocodone	292	103
Hydromorphone	299	100
Hydromorphone-3β-Glucuronide	45,439	0.7
Norhydrocodone	2,277	13.2
Dihydrocodeine	>100,000	<0.3

Cross-reactivity of structurally related or unrelated opiate compounds

Compound	Concentration Tested (ng/mL)	POS/NEG	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

Structurally unrelated compounds

Compound	Concentration Tested (ng/mL)	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
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
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

Interference

Endogenous Substances

High concentrations of the following endogenous substances were added into hydrocodone-spiked urine (± 25% of the cutoff concentration). No interference was observed when tested with the ARK Hydrocodone Assay.

Compound	Concentration Tested (mg/dL)	225 ng/mL (-25% Cutoff)	375 ng/mL (+25% Cutoff)
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 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

Interference – Boric Acid

One percent (1%) w/v of boric acid was added into hydrocodone-spiked urine (± 25% of the cutoff concentration). Results are provided in the table below.

Compound	Concentration Tested	225 ng/mL (-25% Cutoff)	375 ng/mL (+25% Cutoff)
Boric Acid	1% w/v	NEG	NEG

Specific Gravity

Urine samples with specific gravity values ranging from 1.000 to 1.030 were tested in the presence of the two levels of hydrocodone at ± 25% of the 300 ng/mL cutoff concentration. No interference was observed when tested with the ARK Hydrocodone Assay in both qualitative and semi-quantitative modes.

Compound Tested	225 ng/mL Hydrocodone N=3 (POS/NEG)	375 ng/mL Hydrocodone N=3 (POS/NEG)
Specific Gravity 1.0000	NEG	POS
Specific Gravity 1.0021	NEG	POS
Specific Gravity 1.0043	NEG	POS
Specific Gravity 1.0179	NEG	POS
Specific Gravity 1.0187	NEG	POS
Specific Gravity 1.0262	NEG	POS
Specific Gravity 1.0303	NEG	POS

pH

Urine samples with pH values from 3.0 to 11.0 were tested in the presence of the two levels of hydrocodone at ± 25% of the 300 ng/mL cutoff concentration. No interference was observed when tested with the ARK Hydrocodone Assay in both qualitative and semi-quantitative modes.

Compound Tested	225 ng/mL Hydrocodone N=3 (POS/NEG)	375 ng/mL Hydrocodone N=3 (POS/NEG)
Urine pH 3	NEG	POS
Urine pH 4	NEG	POS
Urine pH 5	NEG	POS
Urine pH 6	NEG	POS
Urine pH 7	NEG	POS
Urine pH 8	NEG	POS
Urine pH 9	NEG	POS
Urine pH 10	NEG	POS
Urine pH 11	NEG	POS

Method Comparison

Two hundred twenty-six (226) unaltered clinical urine specimens that are not individually identifiable were analyzed by ARK Hydrocodone Assay in both qualitative and semi-quantitative modes and the results were compared to LC-MS/MS. The overall concordance between LC-MS/MS and the ARK Hydrocodone Assay was 92.5%.

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

ARK Hydrocodone Assay 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

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

ARK Hydrocodone Assay 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

***Discordant Results**

Sample #	ARK Qualitative (POS/NEG)	LC-MS/MS (ng/mL)			ARK Semi-quantitative (ng/mL)
		Hydrocodone	Hydromorphone	Adjusted Total	
3	POS	287.8	210.0	497.8	476.0
15	POS	226.9	150.5	377.4	390.0
18	POS	156.0	174.7	330.8	335.2
23	POS	5.4	1317.7	1323.1	387.7
38	NEG	306.5	22.4	328.9	277.6
39	POS	162.0	52.4	214.5	316.1
48	POS	200.5	61.7	262.2	358.4
51	POS	174.4	29.0	203.4	357.4
66	POS	146.7	190.3	337.0	463.1
68	POS	181.2	150.3	331.5	382.2
70	POS	Not Detected	545.7	545.7	445.7
75	POS	5.9	10524.1	10530.0	2549.1
86	POS	255.8	30.7	286.5	471.4
90	POS	106.5	214.0	320.4	335.5
97	POS	Not Detected	1769.8	1769.8	501.3
99	POS	Not Detected	706.1	706.1	657.9
101	POS	Not Detected	5461.7	5461.7	2014.2

Seventeen (17) samples were considered discordant relative to the ARK Hydrocodone 300 ng/mL cutoff. Cross-reactivity to the major metabolite hydromorphone contributed to the positive results for samples with <300 ng/mL hydrocodone by LC-MS/MS. Sample #38 tested negative and had semi-quantitative results within 25% of the cutoff.

Traceability and Value Assignment

ARK Hydrocodone Calibrators and Controls are prepared by volumetric dilution of high purity hydrocodone (certified solution traceable to HPLC) into non-sterile, processed human urine free of hydrocodone. Testing is performed with the ARK Hydrocodone Assay on the Beckman Coulter AU680 automated clinical chemistry analyzer, calibrated with the ARK Hydrocodone Calibrator.

Calibration Curve Stability

A stored calibration curve was effective up to at least 14 days based on supporting data. Calibration curve stability may depend on individual laboratory performance.

807.92 (b)(3): Conclusions from Nonclinical Testing

As summarized above, the ARK Hydrocodone Assay is substantially equivalent to the legally marketed predicate device, DRI Hydrocodone Assay (K150502) for the declared intended use. Substantial equivalence has been demonstrated through a comparison of the intended use and device characteristics when comparing the subject device to the legally marketed predicate. Performance testing was completed to verify that the device functions as intended and that design specifications have been satisfied. The content of the pre-market notification for the DRI Hydrocodone Assay provides evidence that the device is safe and effective for the intended use.