November 20, 2024

Eterbio, Inc.
% Jenny Xia
Director
LSI International Inc
504 E Diamond Ave
Suite H
Gaithersburg, Maryland 20877

Re: K243064
Trade/Device Name: ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold); ETERBIO Fentanyl/Norfentanyl Home Test
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: NGL
Dated: September 26, 2024
Received: September 27, 2024

Dear Jenny Xia:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2024.11.20 09:04:19 -05'00'

Joseph Kotarek, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243064

Device Name
ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold)
ETERBIO Fentanyl/Norfentanyl Home Test

Indications for Use *(Describe)*
The ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold) is an immunoassay intended for the qualitative detection of Fentanyl (FTY) /Norfentanyl (NFTY) in human urine:

Drug (Identifier)	Calibrator	Cut-off Level
Fentanyl (FYL)	Fentanyl	1ng/mL
Norfentanyl (NFYL)	Norfentanyl	5ng/mL

The test is available as a single panel for FYL or NFYL, or as a dual panel combining both FYL and NFYL. It provides a preliminary screening result only. For a confirmed analytical outcome, a more specific chemical method is required. GC/MS or LC/MS is the preferred confirmatory method.

The ETERBIO Fentanyl/Norfentanyl Home Test is an immunoassay intended for the qualitative detection of Fentanyl (FTY) /Norfentanyl (NFTY) in human urine:

Drug (Identifier)	Calibrator	Cut-off Level
Fentanyl (FYL)	Fentanyl	1ng/mL
Norfentanyl (NFYL)	Norfentanyl	5ng/mL

The test is available as a single panel for FYL or NFYL, or as a dual panel combining both FYL and NFYL. This test provides only preliminary results. For a confirmed analytical outcome, a more specific chemical method is required. GC/MS or LC/MS is the preferred confirmatory method.

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.

510(k) SUMMARY

K243064

1. Date: October 21, 2024

2. Submitter: Eterbio, Inc.
420, No. 1316, Caixia Street, Zhuhai, Guangdong
China

3. Contact person: Jenny Xia
LSI International Inc.
504E Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: jxia@lsi-consulting.org

4. Device Names: ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold)
ETERBIO Fentanyl/Norfentanyl Home Test

Classification: Class 2

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

5. Predicate Devices:

Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel (K241969)

6. Indications for Use

The ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold) is an immunoassay intended for the qualitative detection of Fentanyl (FTY) /Norfentanyl (NFTY) in human urine:

Drug (Identifier)	Calibrator	Cut-off Level
Fentanyl (FYL)	Fentanyl	1ng/mL
Norfentanyl (NFYL)	Norfentanyl	5ng/mL

The test is available as a single panel for FYL or NFYL, or as a dual panel combining both FYL and NFYL. It provides a preliminary screening result only. For a confirmed analytical outcome, a more specific chemical method is required. GC/MS or LC/MS is the preferred confirmatory method.

The ETERBIO Fentanyl/Norfentanyl Home Test is an immunoassay intended for the qualitative detection of Fentanyl (FTY) /Norfentanyl (NFTY) in human urine:

Drug (Identifier)	Calibrator	Cut-off Level
Fentanyl (FYL)	Fentanyl	1ng/mL
Norfentanyl (NFYL)	Norfentanyl	5ng/mL

The test is available as a single panel for FYL or NFYL, or as a dual panel combining both FYL and NFYL. This test provides only preliminary results. For a confirmed analytical outcome, a more specific chemical method is required. GC/MS or LC/MS is the preferred confirmatory method.

7. Device Description

The ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold) and ETERBIO Fentanyl/Norfentanyl Home Test are immunoassays intended for the qualitative detection of fentanyl and norfentanyl in human urine. Each ETERBIO fentanyl/norfentanyl urine test device consists of a Test Panel and a package insert. Each Test Panel is sealed with sachets of desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the ETERBIO Fentanyl Test and the predicate devices is provided in following table.

Table 1: Features Comparison of ETERBIO Fentanyl/Norfentanyl Test and the Predicate Device

Item	Device	Predicate – K241969
Indication(s) for Use	For the qualitative determination of fentanyl in human urine.	Same
Calibrator and Cut-Off Values	Fentanyl (FTY) 1 ng/ml Norfentanyl (NFTY) 5 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For OTC use	Same
Configurations	Panel	Same
Storage	2-30˚C	Same

9. Test Principle

The ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold) and ETERBIO Fentanyl/Norfentanyl Home Test are immunoassays based on the principle of competitive binding.

During testing, a urine specimen migrates upward by capillary action. Each target drug, if present in the urine specimen below its cutoff, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized drug conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the drug level exceeds the cutoff because it will saturate all the binding sites of anti-drug antibodies.

To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off for each target drug. These samples were prepared by spiking fentanyl or norfentanyl in negative urine samples. Each fentanyl or norfentanyl concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed six tests per day per device lot for 10 days in a randomized order.

Fentanyl

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	60-/0+	27+/33-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	59-/1+	26+/34-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	60-/0+	26+/34-	60+/0-	60+/0-	60+/0-	60+/0-

Norfentanyl

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	60-/0+	60-/0+	60-/0+	58-/2+	27+/33-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	58-/2+	26+/34-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	59-/1+	26+/34-	60+/0-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 36-86F for 24 months based on the real stability study.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drug fentanyl urine with concentrations at 50% below and 50% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL or specified concentrations are summarized in the following tables.

Acetaminophen	Creatinine	Ketamine	Perphenazine
Acetone (1000mg/dL)	Cyclobenzaprine	Ketoprofen	Phencyclidine
Acetophenetidin	Deoxycorticosterone	Labetalol	Phenelzine
Acetylsalicylic acid	Desipramine	Lidocaine	Phenobarbital
Albumin (100mg/dL)	Dextromethorphan	Loperamide	Prednisone
Albuterol	Diclofenac	Maprotiline	Propoxyphene
Aminopyrine	Diflunisal	Meperidine	Propranolol
Amitriptyline	Digoxin	Meprobamate	Pseudoephedrine
Amobarbital	Diphenhydramine	Methapyrilene	Quinine
Amoxicillin	DL-Tryptophan	Methaqualone	Ranitidine
Ampicillin	DL-Tyrosine	Methoxyphenamine	Riboflavin (10mg/dL)
Apomorphine	Doxepin	Metronidazole	Salicylic acid
Ascorbic acid	Ecgonine methyl ester	N-Acetylprocainamide	Secobarbital
Aspartame	Ephedrine	NaCl (4000mg/dL)	Serotonin(5-Hydroxytyramine)
Atropine	Erythromycin	Nalidixic acid	Sulfamethazine
Benzilic acid	Ethanol (1%)	Naloxone	Sulindac
Benzoic acid	Fenoprofen	Naltrexone	Tetrahydrocortisone 3-(β-Dglucuronide)
Benzoylecgonine	Fluphenazine	Naproxen	Tetrahydrocortisone 3-acetate
Bilirubin	Furosemide	Niacinamide	Tetrahydrozoline
Boric Acid (1%)	Galactose (10mg/dL)	Nicotine	Thiamine

Bupropion	Gamma Globulin (500mg/dL)	Nifedipine	Thioridazine
Caffeine	Gentisic acid	Norethindrone	Triamterene
Carbamazepine	Glucose (3000mg/dL)	Nortriptyline	Trifluoperazine
Chloral hydrate	Hemoglobin	Noscapine	Trimethoprim
Chloramphenicol	Hydralazine	O-Hydroxyhippuric acid	Tyramine
Chlorothiazide	Hydrochlorothiazide	Octopamine	Urea (2000mg/dL)
Chlorpromazine	Hydrocortisone	Oxalic acid (100mg/dL)	Uric acid
Cholesterol	Hydroxytyramine	Oxazepam	Valproic acid (250µg/mL)
Clomipramine	Ibuprofen	Oxolinic acid	Venlafaxine
Clonidine	Imipramine	Oxymetazoline	Verapamil
Cortisone	Isoproterenol	Papaverine	Zomepirac
Cotinine	Isoxsuprine (10µg/mL)	Penicillin G	β-Estradiol
α-Estradiol	Estrone	7-Aminonitrazepam	Fenfluramine
Fenofibrate	Amlodipine besylate	Phentermine	Phenylethylamine
Fotemustine	Promazine	Promethazine	Gemfibrozil
Aspirin	Gentisic acid	Pyridoxine	Baclofen
Guaiacolglyceryl ether	Pyrilamine	Pyrogallol	Benzocaine
Hexobarbital	Quinidine	Quinolinic Acid	Benzylpiperiazine
Hydroxybutyric Acid	Bromo-2,5,Dimethoxyphenethylamine	Sodium Azide	Carisoprodol
Cetirizine	Lamotrigine	Tetracycline	Lisinopril
Chlordiazepoxide	Loratidine	Chlorpheniramine	Trifluoromethylphenyl-piperazine
Clofibrate	Tryptamine	Metoprolol	Creatine Hydrate
N-desmethyl Tapentadol	γ-Cyclodextrin	Zolpidem	Cyproheptadine
Demoxepam	7-Aminoflunitrazepam	Metformin	Norpseudoephedrine
Nicotinic Acid	Oxazepam Glucuronide	Lorazepam Glucuronide	LSD
Dimethyl-aminoantipyrine	THC	L-thyroxine	Diphenylhydantoin
Methylphenidate	Norpropoxyphene		

e. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of device. The lowest concentration that caused a positive result for each compound are listed below.

Fentanyl (Cutoff=1ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(±) β-hydroxythiofentanyl	2.8	35.7%
(±)-3-cis-methyl fentanyl	5	20%
4-Fluoro-isobutyrylfentanyl	3	33.3%
9-Hydroxy Risperidone	10000	0.01%
Acetyl fentanyl	1.2	83.3%
Acetyl norfentanyl	10000	0.01%
Acrylfentanyl	1.2	83.3%
Alfentanil	100000	0.001%
Butyryl fentanyl	1.6	62.5%
Carfentanil	500	0.20%
Despropionyl fentanyl (4-ANPP)	50000	0.002%
Fentanyl	1	100%
Furanyl fentanyl	1.75	57.1%
Isobutyryl fentanyl	1.5	66.7%
Labetalol Hydrochloride	100000	0.001%
MT-45	10000	0.01%
Norcarfentanil	10000	0.01%

Norfentanyl	5000	0.02%
Ocfentanil	1.5	66.7%
Para-fluoro fentanyl	3	33.3%
Para-fluorobutyryl fentanyl	3	33.3%
Remifentanil	10000	0.01%
Risperidone	1000	0.1%
Sufentanil	625	0.16%
Thienyl Fentnayl	1000	0.1%
Trans-d, I 3-Methylfentanyl	1000	0.1%
Trazodone	1000	0.1%
U-47700	100000	0.001%
Valeryl fentanyl	2.5	40 %
ω- 1-Hydroxyfentanyl	20000	0.005%

Norfentanyl (Cutoff=5ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(±) β-hydroxythiofentanyl	7	71.4%
(±)-3-cis-methyl fentanyl	10	50%
4-Fluoro-isobutyrylfentanyl	25	20%
9-Hydroxy Risperidone	10000	0.05%
Acetyl fentanyl	10	50%
Acetyl norfentanyl	200	2.5%
Acry lfentanyl	10	50%
Alfentanil	>100000/mL	<0.001%
Butyryl fentanyl	10	50%
Carfentanil	>100000/mL	<0.001%
Despropionyl fentanyl (4-ANPP)	>100000/mL	<0.001%
Fentanyl	15	33.3%
Furanyl fentanyl	9	55.6%
Isobutyryl fentanyl	8	62.5%
Labetalol Hydrochloride	20	25%
MT-45	100000	0.005%
Norcarfentanil	5000	0.1%
Norfentanyl	5	100%
Ocfentanil	15	33.3%
Para-fluoro fentanyl	5	100%
Para-fluorobutyryl fentanyl	40	12.5%
Remifentanil	>100000/mL	<0.001%
Risperidone	1000	0.5%
Sufentanil	>100000/mL	<0.001%
Thienyl Fentnayl	50	10%
Trans-d, I 3-Methylfentanyl	50	10 %
Trazodone	>100000/mL	<0.001%

U-47700	100000	0.005%
Valeryl fentanyl	100	5%
ω- 1-Hydroxyfentanyl	500	1%

The following opioids compounds were tested at a concentration of 100ug/mL. Negative results were obtained for all these compounds. There is no cross-reactivity for these compounds using the ETERBIO Device.

6-Acetyl morphine	Naloxone
Amphetamine	Naltrexone
Buprenorphine	Norbuprenorphine
Buprenorphineglucuronide	Norcodeine
Codeine	Norketamine
Dextromethorphan	Normeperidine
Dihydrocodeine	Normorphine
EDDP	Noroxycodone
EMDP	Oxycodone
Fluoxetine	Oxymorphone
Heroin	Pentazocine (Talwin)
Hydrocodone	Pipamperone
Hydromorphone	Tapentadol
Ketamine	Thioridazine
Levorphanol	Tilidine
Meperidine	Tramadol
Methadone	Tramadol-O-Desmethyl
Morphine	Tramadol-N-Desmethyl
Morphine-3-glucuronide	

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with targets fentanyl and norfentanyl at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of device. Results were all positive for samples at and above +50% Cut-Offs and all negative for samples at and below -50% Cut-Offs.

2. Comparison Studies

Method comparison studies for the ETERBIO Fentanyl/Norfentanyl Test were performed by three different operators. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below.

Fentanyl

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Operator 1	Positive	0	0	2	19	20
	Negative	8	16	14	1	0

Operator 2	Positive	0	0	1	18	20
	Negative	8	16	15	2	0
Operator 3	Positive	0	0	2	20	20
	Negative	8	16	14	0	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1	MF046	0.986	+
Operator 1& Operator 3	MF079	0.937	+
Operator 2	MF062	0.925	+
Operator 3	MF058	0.914	+
Operator 2	MF016	1.02	-
Operator 1	MF060	1.01	-
Operator 2	MF063	1.09	-

Norfentanyl

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Operator 1	Positive	0	0	1	19	20
	Negative	8	17	14	1	0
Operator 2	Positive	0	0	1	19	20
	Negative	8	17	14	1	0
Operator 3	Positive	0	0	1	20	20
	Negative	8	17	14	0	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1	MC083	5.2	-
Operator 2	MC019	5.25	-
Operator 1 & Operator 2	MC048	4.85	+
Operator 3	MC009	4.68	+

3. Lay-user study

A lay user study was performed at three testing sites with 140 lay persons. They had diverse educational and professional backgrounds and ranged in age from 18 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-offs by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

% of Cutoff	Number	Fentanyl Concentration	Lay person results	The

	of samples	by LC/MS (ng/mL)	No. of Positive	No. of Negative	percentage of correct results (%)
-100% Cutoff	20	0	0	20	100.0%
-75% Cutoff	20	0.25	0	20	100.0%
-50% Cutoff	20	0.52	0	20	100.0%
-25% Cutoff	20	0.75	1	19	95.0%
+25% Cutoff	20	1.30	20	0	100.0%
+50% Cutoff	20	1.55	20	0	100.0%
+75% Cutoff	20	1.65	20	0	100.0%

% of Cutoff	Number of samples	Norfentanyl Concentration by LC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100.0%
-75% Cutoff	20	1.27	0	20	100.0%
-50% Cutoff	20	2.54	0	20	100.0%
-25% Cutoff	20	3.78	0	20	100.0%
+25% Cutoff	20	6.55	20	0	100.0%
+50% Cutoff	20	7.85	20	0	100.0%
+75% Cutoff	20	8.95	20	0	100.0%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

4. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison and Lay-user studies of the devices, it's concluded a substantial equivalence decision.