Qingdao HIGHTOP Biotech Co., Ltd.
% Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K241969
Trade/Device Name: Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel; Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: NGL
Dated: July 3, 2024
Received: July 5, 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.

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: 2024.08.14 16:18:29 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k241969

Device Name
Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel
Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel

Indications for Use *(Describe)*
Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative detection of fentanyl and norfentanyl, the major metabolite of fentanyl in human urine at the cut-off concentrations listed below:

Analyte	Cut-off Level
Fentanyl (FYL)	1ng/mL
Norfentanyl (NFYL)	5ng/mL

The test is available in a single test of FYL or NFYL or a Double panel of FYL and NFYL. It is intended for OTC use. The test provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative detection of fentanyl and norfentanyl, the major metabolite of fentanyl in human urine at the cut-off concentrations listed below:

Analyte	Calibrator	Cut-off level
Fentanyl (FYL)	Fentanyl	1ng/mL
Norfentanyl (NFYL)	Norfentanyl	5ng/mL

The test is available in a single test of FYL or NFYL or a Double panel of FYL and NFYL.
The test panel provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

The test panel is not intended to distinguish between prescription use or abuse of fentanyl. Clinical consideration and professional judgment should be applied to the test result, particularly in evaluating a preliminary positive result.

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.

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510(k) SUMMARY

K241969

1. Date: July 3, 2024

2. Submitter: Qingdao HIGHTOP Biotech Co., Ltd.
No.369 Hedong Road, Qingdao, Shandong 266112
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: Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel
Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel

Classification: Class 2

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

5. Predicate Devices:

AllTest Fentanyl Urine Test Cassette (K233417)

6. Indications for Use

Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative detection of fentanyl and norfentanyl, the major metabolite of fentanyl in human urine at the cut-off concentrations listed below:

Analyte	Cut-off Level
Fentanyl (FYL)	1ng/mL
Norfentanyl (NFYL)	5ng/mL

The test is available in a single test of FYL or NFYL or a Double panel of FYL and NFYL. It is intended for OTC use.

The test provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel is a competitive binding, lateral flow immunochromatographic assay for qualitative detection of fentanyl and norfentanyl, the major metabolite of fentanyl in human urine at the cut-off concentrations listed below:

Analyte	**Calibrator**	**cut-off level**
Fentanyl (FYL)	Fentanyl	1ng/mL
Norfentanyl (NFYL)	Norfentanyl	5ng/mL

The test is available in a single test of FYL or NFYL or a Double panel of FYL and NFYL.

The test panel provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

The test panel is not intended to distinguish between prescription use or abuse of fentanyl. Clinical consideration and professional judgment should be applied to the test result, particularly in evaluating a preliminary positive result.

7. Device Description

The Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel and Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel are immunoassays intended for the qualitative detection of fentanyl and norfentanyl in human urine. Each Hightop® 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 Hightop® Fentanyl Test and the predicate devices is provided in following table.

Table 1: Features Comparison of Hightop® Fentanyl Urine Test and the Predicate Device

Item	Device	Predicate – K233417
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	Fentanyl (FTY) 1 ng/ml
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	Cassette
Storage	2-30˚C	4-30˚C

9. Test Principle

The Hightop® Home Use Fentanyl/Norfentanyl Urine Rapid Test Panel and Hightop® Fentanyl/Norfentanyl Urine Rapid Test Panel 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 for 10 days per device lot 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+	40+/20-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	59-/1+	38+/22-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	59-/1+	38+/22-	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+	35+/25-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	58-/2+	32+/28-	60+/0-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	59-/1+	33+/27-	60+/0-	60+/0-	60+/0-	60+/0-

c. Stability

The devices are stable at 36-86F for 24 months based on the accelerate 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	Ecgonine methyl ester	Oxolinic acid
Acetone (1000 mg/dL)	Ephedrine	Oxymetazoline
Acetophenetidin	Erythromycin	Papaverine
Acetylsalicylic acid	Estradiol	Penicillin G
Albumin (100 mg/dL)	Estrone	Perphenazine
Albuterol	Ethanol (1%)	Phencyclidine
7-Aminonitrazepam	Fenfluramine	Phenelzine
Amitriptyline	Fenofibrate	Phenobarbital

Amlodipine besylate	Fenoprofen	Phentermine
Amobarbital	Fluphenazine	Phenylethylamine
Amoxicillin	Fotemustine	Prednisone
Ampicillin	Furosemide	Promazine
Apomorphine	Galactose	Promethazine
Ascorbic acid	γ-Globulin (500 mg/dL)	Propoxyphene
Aspartame	Gemfibrozil	Propranolol
Aspirin	Gentisic acid	Pseudoephedrine
Atropine	Glucose (3000 mg/dL)	Pyridoxine
Baclofen	Guaiacolglyceryl ether	Pyrilamine
Benzilic acid	Hemoglobin	Pyrogallol
Benzocaine	Hexobarbital	Quinidine
Benzoic acid	Hydralazine	Quinine
Benzoylecgonine	Hydrochlorothiazide	Quinolinic Acid
Benzylpiperiazine	Hydrocortisone	Ranitidine
Bilirubin	Hydroxybutyric Acid	Riboflavin
Boric Acid (1%)	Ibuprofen	Salicylic acid
Bromo-2,5,Dimethoxyphenethylamine	Imipramine	Secobarbital
Bupropion	Isoproterenol	Serotonin
Caffeine	Isoxsuprine (10 μg/mL)	Sodium Azide
Carbamazepine	Ketoprofen	Sulfamethazine
Carisoprodol	Labetalol	Sulindac
Cetirizine	Lamotrigine	Tetracycline
Chloral hydrate	Lidocaine	Tetrahydrocortisone3-(β-Dglucuronide)
Chloramphenicol	Lisinopril	Tetrahydrocortisone 3-acetate
Chlordiazepoxide	Loperamide	Tetrahydrozoline
Chlorothiazide	Loratidine	Thiamine
Chlorpheniramine	Maprotiline	Triamterene
Chlorpromazine	Meperidine	Trifluoperazine
Cholesterol	Meprobamate	Trifluoromethylphenyl-piperazine
Clofibrate	Methapyrilene	Trimethoprim
Clomipramine	Methaqualone	Tryptamine
Clonidine	Methoxyphenamine	Tyramine
Cortisone	Methylphenidate	Urea (2000 mg/dL)
Cotinine	Metoprolol	Uric acid
Creatine Hydrate	Metronidazole	Valproic acid (250 μg/mL)
Creatinine	N-Acetylprocainamide	Venlafaxine
Cyclobenzaprine	N-desmethyl Tapentadol	Verapamil
γ-Cyclodextrin	Nacl (4000 mg/dL)	Zolpidem
Cyproheptadine	Nalidixic acid	Zomepirac
Demoxepam	Naproxen	7-Aminoflunitrazepam
Deoxycorticosterone	Niacinamide	Metformin
Desipramine	Nicotine	Norpseudoephedrine
Diclofenac	Nicotinic Acid	Oxazepam Glucuronide
Diflunisal	Nifedipine	Lorazepam Glucuronide

Digoxin	Norethindrone	LSD
Dimethyl-aminoantipyrine	Norpropoxyphene	THC
Diphenhydramine	Nortriptyline	L-thyroxine
Diphenylhydantoin	Noscapine	Dextromethorphan
DL-Tryptophan	O-Hydroxyhippuric acid	Ketamine
DL-Tyrosine	Octopamine	Thioridazine
Dopamine (Hydroxytyramine)	Oxalic acid (100mg/dL)	
Doxepin	Oxazepam	

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 in ng/mL. If no cross reactivity was observed then the highest concentration tested is listed.

Fentanyl (Cutoff=1ng/mL)	**Minimum concentration required to obtain a positive result**	**% Cross-Reactivity**
Fentanyl	1	100
Norfentanyl	>100000	<0.001
4-Fluoro-isobutyryl fentanyl	200	0.5
9-Hydroxy Risperidone	10000	0.01
Acetyl fentanyl	5	20
Acetyl Norfentanyl	>100000	<0.001
(±)-β-hydroxythiofentanyl	25	4
Acryl fentanyl	5	20
Alfentanil	10000	0.01
Butyryl fentanyl	10	10
Carfentanil	10	10
(±)-cis-3-methylfentanyl	1000	0.1
Despropionyl fentanyl (4-ANPP)	10000	0.01
Furanyl Fentanyl	20	5
Isobutyryl Fentanyl	50	2
Labetalol Hydrochloride	>100000	<0.001
MT-45	10000	0.01
Norcarfentanil	>20000	<0.005
Ocfentanil	1000	0.1
Para-fluorobutyryl Fentanyl (PFBF)	20	5
Para-fluoro Fentanyl	20	5
Remifentanil	>20000	<0.005
Risperidone	1000	0.1
Sufentanil	1000	0.1
Thienyl Fentnayl	1000	0.1
Trans-d, I 3-Methylfentanyl	1000	0.1
Trazodone	1000	0.1

U-47700	>100000	<0.001
Valeryl fentanyl	50	2
ω-1-Hydroxyfentanyl	>20000	<0.005

Norfentanyl (Cutoff=5ng/mL)	**Minimum concentration required to obtain a positive result**	**% Cross-Reactivity**
Norfentanyl	5	100
Fentanyl	9	55.6
4-Fluoro-isobutyryl fentanyl	>20000	<0.025
9-Hydroxy Risperidone	10000	0.05
Acetyl fentanyl	150	3.3
Acetyl Norfentanyl	200	2.5
(±)-β-hydroxythiofentanyl	20	25
Acryl fentanyl	50	10
Alfentanil	1000	0.5
Butyryl fentanyl	10	50
Carfentanil	10000	0.05
(±)-cis-3-methylfentanyl	50	10
Despropionyl fentanyl (4-ANPP)	>20000	<0.025
Furanyl Fentanyl	50	10
Isobutyryl Fentanyl	1000	0.5
Labetalol Hydrochloride	>100000	<0.005
MT-45	5000	0.1
Norcarfentanil	>20000	<0.025
Ocfentanil	500	1
Para-fluorobutyryl Fentanyl (PFBF)	20	25
Para-fluoro Fentanyl	10	50
Remifentanil	10000	0.05
Risperidone	1000	0.5
Sufentanil	1000	0.5
Thienyl Fentnayl	50	10
Trans-d, I 3-Methylfentanyl	50	10
Trazodone	10000	0.05
U-47700	>100000	<0.005
Valeryl fentanyl	>20000	<0.025
ω-1-Hydroxyfentanyl	>20000	<0.025

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 Hightop® 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 Hightop® Fentanyl Urine 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	10	13	15	1	0
Operator 2	Positive	0	0	2	19	20
	Negative	10	13	15	1	0
Operator 3	Positive	0	0	1	19	20
	Negative	10	13	16	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1, 3	SE086 & SE156	0.7880	Positive
Operator 1, 2	SE052 &SE169	0.7912	Positive
Operator 1	SE031	1.0078	Negative

Operator 2	SE110	0.7874	Positive
Operator 2	SE182	1.0282	Negative
Operator 3	SE240	1.0811	Negative

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	10	13	16	1	0
Operator 2	Positive	0	0	2	18	20
	Negative	10	13	15	2	0
Operator 3	Positive	0	0	1	19	20
	Negative	10	13	16	1	0

Discordant Results

Operator	Sample ID	LC/MS Result (ng/mL)	Rapid Test Result
Operator 1, 2	SF133 & SF107	4.6743	Positive
Operator 1	SF016	5.1608	Negative
Operator 2, 3	SF201 & SF219	4.1946	Positive
Operator 2	SF231	5.1303	Negative
Operator 2, 3	SF088 & SF221	5.0744	Negative

3. Lay-user study

A lay user study was performed at three testing sites using three different lots (1 lot per test site) 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 of samples	Fentanyl 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	0.24	0	20	100.0%
-50% Cutoff	20	0.47	0	20	100.0%
-25% Cutoff	20	0.72	0	20	100.0%
+25% Cutoff	20	1.21	20	0	100.0%
+50% Cutoff	20	1.50	20	0	100.0%
+75% Cutoff	20	1.81	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	1.33	0	20	100.0%
-50% Cutoff	20	2.63	0	20	100.0%
-25% Cutoff	20	4.06	1	19	95.0%
+25% Cutoff	20	6.03	20	0	100.0%
+50% Cutoff	20	7.29	20	0	100.0%
+75% Cutoff	20	9.08	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.