September 20, 2018

Premier Biotech, Inc.
c/o Lisa Pritchard
Regulatory, Quality & Compliance Consultant
DuVal & Associates
825 Nicollet Mall Suite 1820
Minneapolis, MN 55402

Re: k181305
Trade/Device Name: OralTox® Oral fluid Drug Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC, DJG, DIO, DKZ, LCM, LDJ, DJR
Dated: August 9, 2018
Received: August 10, 2018

Dear Lisa Pritchard:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181305

Device Name
OralTox® Oral fluid Drug Test

Indications for Use *(Describe)*
The OralTox® Oral Fluid Drug Test is a competitive binding, lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana (THC), Methamphetamine, Opiates, Phencyclidine, Oxycodone and Methadone in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylecgonine	20
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI)	Morphine	40
Phencyclidine (PCP)	Phencyclidine	10
Oxycodone (OXY)	Oxycodone	20
Methadone (MTD)	Methadone	30

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. It is not intended to detect intermittent dosing of Oxycodone. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary 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.

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k181305

510(k) SUMMARY

1. Date: September 19, 2018

2. Submitter: Premier Biotech Inc
723 Kasota Avenue SE,
Minneapolis MN 55414

3. Contact person: Jackie Gale
Premier Biotech Inc
723 Kasota Avenue SE,
Minneapolis MN 55414

Telephone: 612-839-5565
Email: jgale@premierbiotech.com

4. Device Name: OralTox® Oral fluid Drug Test

Classification:

Product Code	CFR #	Panel
DJC	21 CFR, 862.3610 Methamphetamine Test System	Toxicology
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
LCM	Enzyme Immunoassay Phencyclidine Test	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoids Test System	Toxicology
DJR	21 CFR, 862.3610 Methadone Test System	Toxicology

5. Predicate Devices:

Predicate Device
K171403: OralTox Oral Fluid Drug Test

Reference Devices
K002010: OraSure Methadone Intercept Micro-plate
K122809: Advin Multi-Drug Screen Test Cup

6. Intended Use

The OralTox® Oral Fluid Drug Test is a competitive binding, lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana (THC), Methamphetamine, Opiates, Phencyclidine, Oxycodone and Methadone in human oral fluid at the cutoff concentrations listed below and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylecgonine	20
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI)	Morphine	40
Phencyclidine (PCP)	Phencyclidine	10
Oxycodone (OXY)	Oxycodone	20
Methadone (MTD)	Methadone	30

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry/ Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. It is not intended to detect intermittent dosing of Oxycodone. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

7. Device Description

The OralTox Oral fluid Drug Test is an immunochromatographic assay that uses a lateral flow system for the qualitative detection of Amphetamine, Cocaine, Cannabinoids, Methamphetamine, Morphine, Phencyclidine, Oxycodone and Methadone (target analytes) in human oral fluid. The products are single-use in vitro diagnostic devices. Each test kit contains a test cup, a package insert and a sample collection sponge. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the OralTox Oral fluid Drug Test and the predicate devices is provided in following tables.

Table 1: Features Comparison of OralTox Oral fluid Drug Test and the Predicate and Reference Devices

Item	Subject Device	Predicate Device K171403
Intended Use	For the qualitative determination of drugs of abuse in human oral fluid.	Same

Item	Subject Device	Predicate Device K171403
Calibrators	D-Amphetamine (AMP) Cocaine (COC) Delta-9-Tetrahydrocannabinol (THC) D-Methamphetamine (MET) Morphine (OPI) Phencyclidine (PCP) Oxycodone (OXY) Methadone (MTD)	D-Amphetamine (AMP) Cocaine (COC) Delta-9-Tetrahydrocannabinol (THC) D-Methamphetamine (MET) Morphine (OPI) Phencyclidine (PCP)
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Oral Fluid	Same
Cut-Off Values	AMP 50 ng/mL COC 20 ng/mL THC 40 ng/mL MET 50 ng/mL OPI 40 ng/mL PCP 10 ng/mL OXY 20 ng/mL MTD 30 ng/mL	Same, except OXY and MTD not included

9. Test Principle

The OralTox Oral Fluid Drug Test is a rapid test for the qualitative detection of Amphetamine, Cocaine, Cannabinoids, Methamphetamine, Morphine, Phencyclidine, Oxycodone and Methadone in oral fluid samples. The tests are lateral flow chromatographic immunoassays. During testing, an oral fluid specimen migrates upward by capillary action. If target drugs present in the oral fluid specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. 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 target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the

particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision-Reproducibility-Cut-Off

Precision-Reproducibility-Cut-Off 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. These samples were prepared by spiking drug in negative oral fluid samples. Each drug concentration was confirmed by LC/MS/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 two runs per day for 10 days per device lot in a randomized order. The results obtained are summarized in the following tables for Methadone and Oxycodone. The rest of the data were reported in K171403.

The results summary for methadone

Result / drug	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	Cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
Lot 1	**60-/0+**	**60-/0+**	**60-/0+**	**54-/6+**	**49+/11-**	**55+/5-**	**60+/0-**	**60+/0-**	**60+/0-**
Lot 2	**60-/0+**	**60-/0+**	**60-/0+**	**55-/5+**	**48+/12-**	**56+/4-**	**60+/0-**	**60+/0-**	**60+/0-**
Lot 3	**60-/0+**	**60-/0+**	**60-/0+**	**55-/5+**	**50+/10-**	**55+/5-**	**60+/0-**	**60+/0-**	**60+/0-**

The results summary for oxycodone

Result / drug	-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+**	**55-/5+**	**50+/10-**	**55+/5-**	**60+/0-**	**60+/0-**	**60+/0-**
Lot 2	**60-/0+**	**60-/0+**	**60-/0+**	**54-/6+**	**49+/11-**	**56+/4-**	**60+/0-**	**60+/0-**	**60+/0-**
Lot 3	**60-/0+**	**60-/0+**	**60-/0+**	**56-/4+**	**49+/11-**	**57+/3-**	**60+/0-**	**60+/0-**	**60+/0-**

The following cut-off values for the candidate device have been verified.

Calibrator	Cut-off (ng/mL)
Methadone	30
Oxycodone	20

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C and real time stability study at 2-8°C and 30°C.

d. Interference

Potential interfering substances were added to drug-free oral fluid and target drugs oral fluid with concentrations at 50% below and 50% above Cut-Off levels. These oral fluid samples were tested using three batches of the OralTox device. Compounds that showed no interference for all eight drugs at a concentration of 10µg/mL are summarized in the following table.

Acetaminophen	Digoxin	Nicotinamide
Acetylcodeine	Dihydrocodeine	Nicotine
Allobarbital	diltiazem HCl	Noscapine
Alprazolam	Diphenhydramine HCl	Omeprazole
Amobarbital	DL-Propranolol	Papaverine
Apomorphine	Doxylamine	Pentazocine
Atenolol	Ecgonine methylester	Phentermine
Atropine	Estradiol	Phenylpropanolamine
Baclofen	Estrone	Phenytoin
Benzocaine	Fluconazole	Pioglitazone HCl
Butabarbital	Furosemide	Prednisolone
Caffeine	Hexobarbital	Prednisone
Cannabidiol	Hydrochlorothiazide	Procainamide HCl
Carbamazepine	Ibuprofen	Procaine HCL
Chlordiazepoxide	Imipramine	Promethazine
Chlorpromazine	Lamotrigine	Quinine HCl
Cimetidine	Levetiracetam	R,R(-)-Pseudoephedrine
Citalopram HBr	Lidocaine	Salicylic Acid
Clobazam	Lormetazepam	Sertraline HCL
Clomipramine	L-Thyroxine	Simvastin
Clonazepam	Metformin HCl	Theophylline
Clonidine	Methylphenidate HCl	Thiamine
Clopidogrel bisulfate	Metoprolol	Topiramate
Cortisol	Metronidazole	Valproic Acid
Cotinine	Montelukast sodium salt	Verapamil
d,l-Salbutamol	Naloxone	Zonisamide
Deoxycorticosterone	Naltrexone	
Dextromethorphan	Naproxen	

Food items such as methanol cough drops, cough syrup, cola, mouthwash, coffee, tea, milk, sugar, chewing gum, alcohol, baking soda, salt, cranberry juice, orange juice, food coloring (red, blue, green), toothpaste, tomatoes and MSG were added in either drug-free oral fluid or oral fluid containing the target drug with concentrations of 50% below and 50% above cutoff levels to a concentration of 5%. None of the substances showed interference.

Hemoglobin showed no interference at 100 µg/mL.

Cigarette smoking showed no interference.

e. Specificity

To test specificity, drug metabolites and other structural related compounds that are likely to interfere in oral fluid samples were tested using three batches of the OralTox device. The results obtained are summarized in the following tables for Methadone and Oxycodone. The rest of the data were reported in K171403.

Oxycodone (Cut-off=20 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
Oxycodone	20	100%
Hydrocodone	1000	2%
Hydromorphone	6250	0.3%
Naloxone	6250	0.3%
Oxymorphone	1000	2%
Dihydrocodeine	Negative at 10000	<0.2%
Buprenorphine	Negative at 10000	<0.2%
6-AM	Negative at 10000	<0.2%
Codeine	Negative at 10000	<0.2%
Heroin	Negative at 10000	<0.2%
Morphine	Negative at 10000	<0.2%
Morphine -3-β-d-glucuronide	Negative at 10000	<0.2%
Ethylmorphine	Negative at 10000	<0.2%

Methadone (Cut-off=30 ng/mL)	**Result Positive at(ng/ml)**	**% Cross-Reactivity**
Methadone	30	100%
Alpha-Methadol	125	24%
Doxylamine	12500	0.24%
2-Ethylidene-1,5-dimethyl-3,3-diphenyl pyrolidine (EDDP)	10000	0.3%
Phencyclidine	12500	0.24%
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	100000	0.03%
LAAM	10000	0.3%

f. Effect of Oral fluid pH

To investigate the effect of oral fluid pH, oral fluid samples with pH 4 to 9 were spiked with target drugs at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of the device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off.

g. Drug Recovery Study

Negative oral fluid samples in glass bottles were spiked with the drug to concentrations of -50% and +50% of the cutoff. The samples were transferred to OralTox devices and stored at room temperature, at -20°C and at 40°C. Over 90% recoveries were observed for all drugs in

the OralTox devices. Oral fluid samples can be stored in the device at -20°C for at least 3 months. Oral fluid samples can be shipped overnight in the device for LC-MS confirmation.

2. Method Comparison Studies

Method comparison studies for the OralTox Oral fluid Drug Test were performed at eight testing sites with three operators at each site. Operators tested total 932 samples and compared to LC/MS/MS results. The results obtained are summarized in the following tables for Oxycodone and Methadone. The rest of the data were reported in K171403.

Oxycodone

% of Cutoff	Number of samples	OralTox Results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug Free	**152**	**0**	**152**	**100**
Less than Half the Cutoff Concentration by LC/MS	**47**	**0**	**47**	**100**
Near Cutoff Negative	**32**	**5**	**27**	**84.4**
Near Cutoff Positive	**29**	**25**	**4**	**86.2**
High Positive	**174**	**174**	**0**	**100**

Discordant Results of Oxycodone

Sites	Sample Number	LC/MS Result	Test Results
Site B	82509	18.0	Positive
Site C	66855	17.2	Positive
Site G	59102	19.05	Positive
Site G	55774	18.23	Positive
Site G	58969	18.52	Positive
Site G	58466	23.29	Negative
Site G	54039	22.04	Negative
Site G	59304	22.4	Negative
Site G	59839	22.34	Negative

Methadone

% of Cutoff	Number of samples	OralTox Results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug Free	**277**	**0**	**277**	**100**

Less than Half the Cutoff Concentration by LC/MS	**13**	**0**	**13**	**100**
Near Cutoff Negative	**20**	**4**	**16**	**80**
Near Cutoff Positive	**15**	**13**	**2**	**87**
High Positive	**173**	**173**	**0**	**173**

Discordant Results of Methadone

Sites	Sample Number	LC/MS Result	Test Results
Site D	37797	26.9	Positive
Site E	29605	27.85	Positive
Site H	59547	28.26	Positive
Site H	50075	28.82	Positive
Site D	26326	31.07	Negative
Site H	53132	31.29	Negative

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, interference, specificity, and method comparison studies of the devices, it's concluded that the OralTox Oral fluid Drug Test is substantially equivalent to the stated predicate device.