February 21, 2018

MICROGENICS CORPORATION
MINOTI PATEL
MANAGER, REGULATORY AFFAIRS
46500 KATO ROAD
FREMONT, CA 94538

Re: K173963
Trade/Device Name: DRI Benzodiazepine Assay
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: Class II
Product Code: JXM
Dated: December 27, 2017
Received: December 28, 2017

Dear Minoti Patel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
k173963

Device Name
DRI Benzodiazepine Assay

Indications for Use *(Describe)*

The DRI Benzodiazepine Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of the presence of benzodiazepines and their metabolites in human urine at a cutoff concentration of 200 ng/mL. The assay is intended to be used in laboratories and provides a simple and rapid analytical screening procedure to detect benzodiazepines in human urine. The assay is designed for use with a number of clinical chemistry analyzers. This assay is calibrated against Oxazepam. This product is intended to be used by trained professionals only.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.

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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k173963

510(k) Summary

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

A. Device Information

Category	Comments
Sponsor:	Microgenics Corporation Thermo Fisher Scientific 46500 Kato Road Fremont, CA 94538 Phone: 510-979-5000 FAX: 510-979-5002
Correspondent Contact Information:	Minoti Patel, RAC Manager, Regulatory Affairs Email: Minoti.patel@thermofisher.com Phone: 510-979-5000 FAX: 510-979-5002
Device Common Name:	Benzodiazepine Enzyme Immunoassay
Trade or Proprietary Name	DRI Benzodiazepine Assay
Candidate Device Product Code, Classification, Classification Name & Panel	JXM, Class II, 21 CFR 862.3170 – Benzodiazepine test system, 91 – Toxicology

Predicate Device Information:

Predicate Device:	Benzodiazepine Enzyme Immunoassay
Predicate Device Manufacturer:	Diagnostic Reagents, Inc.
Predicate Device Premarket Notification #:	K930529

B. Date Summary Prepared

February 20, 2018

C. Description of Device

The DRI Benzodiazepine Assay is a homogeneous enzyme immunoassay[3] with liquid ready-to-use reagents. The assay uses a specific antibody which can detect most benzodiazepines and their metabolites in urine. The assay is based on the competition of an enzyme glucose- 6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the enzyme-labeled drug is bound by the specific antibody and the enzyme activity is inhibited. This phenomenon

creates a relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

The assay consists of reagents A and E.

Reagent A: Contains sheep polyclonal anti-benzodiazepine antibodies, glucose-6-phosphate (G6P) and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

Reagent E: Contains benzodiazepine derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

D. Intended Use

DRI Benzodiazepine Assay:

The DRI Benzodiazepine Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of the presence of benzodiazepines and their metabolites in human urine at a cutoff concentration of 200 ng/mL. The assay is intended to be used in laboratories and provides a rapid analytical screening procedure to detect benzodiazepines in human urine. The assay is designed for use with a number of clinical chemistry analyzers. This assay is calibrated against Oxazepam. This product is intended to be used by trained professionals only.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.[1, 2]

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.

E. Comparison to Predicate Device

Characteristic	**Candidate Device:** DRI Benzodiazepine Assay	**Predicate Device:** DRI Benzodiazepine Assay (K930529).
Intended Use	The DRI Benzodiazepine Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of the presence	Same

Characteristic	Candidate Device: DRI Benzodiazepine Assay	Predicate Device: DRI Benzodiazepine Assay (K930529).
	of benzodiazepines and their metabolites in human urine at a cutoff concentration of 200 ng/mL.	
Operating Principle (Technology)	DRI	Same
Measured Analyte	Benzodiazepine and its metabolites	Same
Test Matrix	Urine	Same
Cutoff Levels	200 ng/mL	Same
Methodology	Homogeneous Enzyme Immunoassay	Same
Reagents Form	Liquid ready-to-use.	Same
Antibody	Sheep Polyclonal antibody	Goat Polyclonal antibody
Storage	2–8°C until expiration date.	Same
Principal Operator	Trained professionals	Same

F. Test Principle

The DRI Benzodiazepine Assay is a homogeneous enzyme immunoassay[3] with liquid ready-to-use reagents. The assay uses a specific antibody which can detect most benzodiazepines and their metabolites in urine. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the enzyme-labeled drug is bound by the specific antibody and the enzyme activity is inhibited. This phenomenon creates a relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

G. Summary of Supporting Data

1. **Analytical Performance:**

Performance is evaluated at the manufacturer's site on the AU680 clinical analyzer.

a) **Precision**

Precision studies were performed in accordance with CLSI Guideline EP05-A3. Samples were prepared by spiking Oxazepam into drug free urine at the cutoff, 25%, 50%, 75% and 100% above and below the cutoff and tested in both qualitative and semi-quantitative modes. Results presented below were generated by testing all samples in

replicates of 2, twice per day for 20 days, total n=80. The results are summarized in the table below.

Quantitative Study Analysis

Spiked Concentration (ng/mL)	% of Cutoff (200 ng/mL)	LC-MS/MS (ng/mL)	Total Precision (n=80)	
			# of Determinants	Immunoassay Results (Negative/Positive)
0	-100%	N/A	80	80/0
50	-75%	56.0	80	80/0
100	-50%	102.0	80	80/0
150	-25%	161.5	80	80/0
200	100%	214.0	80	16/64
250	+25%	255.5	80	0/80
300	+50%	299.0	80	0/80
350	+75%	348.0	80	0/80
400	+100%	403.0	80	0/80

Semi-Quantitative Study Analysis

Spiked Concentration (ng/mL)	% of Cutoff (200 ng/mL)	LC-MS/MS (ng/mL)	Total Precision (n=80)	
			# of Determinants	Immunoassay Results (Negative/Positive)
0	-100%	N/A	80	80/0
50	-75%	56.0	80	80/0
100	-50%	102.0	80	80/0
150	-25%	161.5	80	80/0
200	100%	214.0	80	27/53
250	+25%	255.5	80	0/80
300	+50%	299.0	80	0/80
350	+75%	348.0	80	0/80
400	+100%	403.0	80	0/80

b) **Spike Recovery**

The study was performed for 20 replicates. This study was carried out by testing spiked samples containing Oxazepam at the cutoff calibrator and control levels. The spiked samples were prepared by spiking Oxazepam into drug free urine. Samples were tested in both Qualitative and Semi-Quantitative mode. The qualitative results are summarized in the table below.

Qualitative Data

Replicates	150 ng/mL (n=20)	250 ng/mL (n=20)
1	Negative	Positive
2	Negative	Positive
3	Negative	Positive
4	Negative	Positive
5	Negative	Positive
6	Negative	Positive
7	Negative	Positive
8	Negative	Positive
9	Negative	Positive
10	Negative	Positive
11	Negative	Positive
12	Negative	Positive
13	Negative	Positive
14	Negative	Positive
15	Negative	Positive
16	Negative	Positive
17	Negative	Positive
18	Negative	Positive
19	Negative	Positive
20	Negative	Positive
Overlap	No	No
Relative to C/O	All 20 below C/O	All 20 above C/O

c) **Analytical Recovery and Linearity**

Linearity studies were performed in accordance with CLSI Guideline EP06-A. To demonstrate the dilution linearity for purposes of sample dilution and quality control of the entire assay range, drug free urine was spiked to the high level calibrator using Oxazepam (1000 ng/mL) and diluted with drug free urine to generate 10 intermediate levels.

Each sample was run in replicates of five in semi-quantitative mode and the average was used to determine percent recovery compared to the expected target value. The percent recovery is summarized in the table below.

Level	**Expected Concentration (ng/mL)**	**Observed Concentration (ng/mL)**	**Recovery (%)**
1	0	-1.0	N/A
2	100	104.5	104.5
3	200	196.2	98.1

Level	Expected Concentration (ng/mL)	Observed Concentration (ng/mL)	Recovery (%)
4	300	314.7	104.9
5	400	455.3	113.8
6	500	565.2	113.0
7	600	661.0	110.2
8	700	764.7	109.2
9	800	872.1	109.0
10	900	937.3	104.1
11	1000	1024.9	102.5

d) **Method Comparison and Accuracy**

The method comparison study was performed in accordance with CLSI Guideline EP09-A3. One hundred and six patient samples were analyzed by the DRI Benzodiazepine 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 DRI Benzodiazepine Assay is 96.2%. The qualitative and semi-quantitative results are summarized in the tables below.

Qualitative Accuracy study with LC-MS/MS as reference method

Candidate Device Results	Negative by LC-MS/MS	< 50% of Cutoff concentration by LC-MS/MS (< 100ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (100 – 199 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (200 – 300 ng/mL)	High Positives (Greater than 50% above cutoff concentration (> 300 ng/mL)
Positive	0	1*	3*	5	45
Negative	48	2	2	0	0

Negative agreement is 52/56 * 100% = 92.9%
Positive agreement is 50/50 * 100% = 100%
Overall agreement is 102/106 * 100% = 96.2%

Semi-Quantitative Mode Accuracy study with LC-MS/MS as reference method

Candidate Device Results	Negative by LC-MS/MS	< 50% of Cutoff concentration by LC-MS/MS (< 100ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration as determined by LC-MS/MS) (100 – 199 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration as determined by LC-MS/MS) (200 – 300 ng/mL)	High Positives (Greater than 50% above cutoff concentration (> 300 ng/mL)
Positive	0	1*	3*	5	45
Negative	48	2	2	0	0

Negative agreement is 52/56 * 100% = 92.9%
Positive agreement is 50/50 * 100% = 100%
Overall agreement is 102/106 * 100% = 96.2%

*Discordant samples

Sample ID	Qualitative	Semi-Quantitative	LC-MS/MS
	Negative/ Positive	Negative/ Positive	Total Benzodiazepine Parent Only (ng/mL)
CA160606-045	Positive	Positive	86.20
CA160926-057	Positive	Positive	175.08
CA170605-001	Positive	Positive	151.52
CA160908-003	Positive	Positive	192.87

These four samples are discordant because of the presence of Benzodiazepine metabolites.
Sample CA160606-045 contains 3154.59 ng/mL 7-Aminoclonazepam .
Sample CA160926-057 contains 13.46 ng/mL α-Hydroxyalprazolam and 410.69 ng/mL 7-Aminoclonazepam.
Sample CA170605-001 contains 1.43 ng/mL α-Hydroxyalprazolam and 560.37 ng/mL 7-Aminoclonazepam.
Sample CA160908-003 contains 96.27 ng/mL α-Hydroxyalprazolam.

e) **Specificity**

The cross-reactivity of benzodiazepine compounds and their metabolites were evaluated by adding known amounts of each compound to drug-free negative urine. The results are summarized in the tables below.

Cross reactivity of benzodiazepine compounds and structurally unrelated compound*

Structurally related and unrelated compounds	Tested Concentration (ng/mL)	Cross-reactivity (%)
α-Hydroxyalprazolam	110	182
α-Hydroxytriazolam	140	143
Alprazolam	110	182

Structurally related and unrelated compounds	Tested Concentration (ng/mL)	Cross-reactivity (%)
7-Aminoclonazepam	2,500	8
7-Aminoflunitrazepam	300	67
7-Aminonitrazepam	300	67
Bromazepam	170	118
Chlordiazepoxide	700	29
Clobazam	150	133
Clonazepam	210	95
Clorazepate	135	148
Delorazepam	150	133
Demoxepam	220	91
Desalkylflurazepam	130	154
Diazepam	110	182
Estazolam	100	200
Flunitrazepam	120	167
Flurazepam	150	133
2-Hydroxyethylflurazepam	120	167
Lorazepam	700	29
Lorazepam glucuronide	50,000	<0.4
Lormetazepam	275	73
Medazepam	325	62
Midazolam	180	111
Nitrazepam	130	154
Norchlordiazepoxide	800	25
Nordiazepam	110	182
*Oxaprozin	125,000	0.16
Oxazepam	200	100
Oxazepam glucuronide	50,000	0.4
Prazepam	200	100
Temazepam	160	125
Temazepam glucuronide	50,000	<0.4
Triazolam	130	154

Structurally unrelated compounds were evaluated by adding each substance to Oxazepam spiked at low control, 150 ng/mL (-25% of the cutoff concentration) and the high control, 250 ng/mL (+25% of the cutoff concentration), at the concentrations indicated. As shown in the table below, the Controls were detected accurately, Low Control as Negative and the High Control as Positive, indicating that all the compounds evaluated exhibited no significant cross-reactivity at the concentrations tested.

Structurally unrelated compounds spiked at the concentration listed below into Low and High control urine

Structurally Unrelated Compounds	Tested Concentration (ng/mL)	Spiked Oxazepam Level	
		Low Control	High Control
		Positive/ Negative	Positive/ Negative
6-Acetyl morphine	100,000	Negative	Positive
10,11 Dihydrocarbamazepine	100,000	Negative	Positive
11-nor-Δ^9-THC-COOH	100,000	Negative	Positive
Acetaminophen	1,000,000	Negative	Positive
Acetylsalicylic acid	1,000,000	Negative	Positive
Amitriptyline	100,000	Negative	Positive
Amoxicillin	100,000	Negative	Positive
Amphetamine	100,000	Negative	Positive
Amisulpride	100,000	Negative	Positive
Benzotropine Mesylate	100,000	Negative	Positive
Benzoylecgonine	100,000	Negative	Positive
Brompheniramine	100,000	Negative	Positive
Buprenorphine	100,000	Negative	Positive
Caffeine	100,000	Negative	Positive
Captopril	100,000	Negative	Positive
Chlorpromazine	100,000	Negative	Positive
Chloroquine	100,000	Negative	Positive
Cimetidine	100,000	Negative	Positive
Clomipramine	100,000	Negative	Positive
Codeine	100,000	Negative	Positive
Desipramine	100,000	Negative	Positive
Dextromethorphan	100,000	Negative	Positive
Digoxin	100,000	Negative	Positive
Dihydrocodeine	100,000	Negative	Positive
Diphenhydramine	500,000	Negative	Positive
Doxepine HCl	100,000	Negative	Positive
EDDP	100,000	Negative	Positive
EMDP	25,000	Negative	Positive
Enalapril	100,000	Negative	Positive
Fentanyl	100,000	Negative	Positive
Fluoxetine	500,000	Negative	Positive
Fluophenazine	100,000	Negative	Positive
Haloperidol	100,000	Negative	Positive
Heroin	100,000	Negative	Positive
Hydrocodone	100,000	Negative	Positive
Hydromorphone	100,000	Negative	Positive
Hydroxychloroquine	100,000	Negative	Positive
Hydroxyzine	100,000	Negative	Positive

Structurally Unrelated Compounds	Tested Concentration (ng/mL)	Spiked Oxazepam Level	
		Low Control	High Control
		Positive/ Negative	Positive/ Negative
Ibuprofen	100,000	Negative	Positive
Imipramine	100,000	Negative	Positive
LAAM	100,000	Negative	Positive
Levorphanol	100,000	Negative	Positive
Levothyroxine	100,000	Negative	Positive
Maprotiline	100,000	Negative	Positive
Meperidine	100,000	Negative	Positive
Methadone	100,000	Negative	Positive
Methamphentamine	100,000	Negative	Positive
Morphine	100,000	Negative	Positive
Morphine-3β-D-glucuronide	100,000	Negative	Positive
Morphine-6β-D-glucuronide	100,000	Negative	Positive
Nalbuphine	100,000	Negative	Positive
Nalorphine	100,000	Negative	Positive
Naloxone	100,000	Negative	Positive
Naltrexone	100,000	Negative	Positive
Naproxen	100,000	Negative	Positive
Nifedipine	100,000	Negative	Positive
Norcodeine	100,000	Negative	Positive
Norhydrocodone	100,000	Negative	Positive
Norfluoxetine	500,000	Negative	Positive
Noroxycodone	100,000	Negative	Positive
Noroxymorphone	100,000	Negative	Positive
Norpropoxyphene	100,000	Negative	Positive
Norsertraline	62,500	Negative	Positive
Nortryptiline	100,000	Negative	Positive
Oxycodone	100,000	Negative	Positive
Oxymorphone	100,000	Negative	Positive
Paroxetine	100,000	Negative	Positive
Perphenazine	100,000	Negative	Positive
Phencyclidine	100,000	Negative	Positive
Phenobarbital	100,000	Negative	Positive
Procyclidine	100,000	Negative	Positive
Propoxyphene	100,000	Negative	Positive
Protriptyline	100,000	Negative	Positive
Ranitidine	100,000	Negative	Positive
Secobarbital	100,000	Negative	Positive
Sertraline	62,500	Negative	Positive
Sulpiride	100,000	Negative	Positive

Structurally Unrelated Compounds	Tested Concentration (ng/mL)	Spiked Oxazepam Level	
		Low Control	High Control
		Positive/ Negative	Positive/ Negative
Tapentadol	100,000	Negative	Positive
Thioridazine	100,000	Negative	Positive
Tramadol	100,000	Negative	Positive
Triprolidine	100,000	Negative	Positive
Verapamil	100,000	Negative	Positive
Zaleplon	100,000	Negative	Positive
Zolpidem	100,000	Negative	Positive
Zopiclone	100,000	Negative	Positive

f) **Interference**

The interference studies were performed in accordance with CLSI Guideline EP07-A2, using both Qualitative and Semi-quantitative modes. The potential interference of pH and endogenous physiologic substances on recovery of Oxazepam using DRI Benzodiazepine Assay was assessed by spiking known compounds of potentially interfering substances into the Low Control, 150 ng/mL (-25% of the cutoff concentration) and High Control, 250 ng/mL (+25% of the cutoff concentration). In the presence of the compounds listed below, the controls were detected accurately, indicating that these compounds did not show interference in the assay.

Interference substances

Compound	Tested Concentration (mg/dL)	Spiked Oxazepam Level	
		Low Control -25% of cutoff (150 ng/mL)	**High Control** +25% of cutoff (250 ng/mL)
Acetone	500	Negative	Positive
Ascorbic acid	150	Negative	Positive
Creatinine	400	Negative	Positive
Ethanol	1000	Negative	Positive
Galactose	5	Negative	Positive
Glucose	1000	Negative	Positive
Hemoglobin	150	Negative	Positive
Human serum albumin	200	Negative	Positive
Oxalic acid	50	Negative	Positive
Riboflavin	3	Negative	Positive
Sodium Chloride	1000	Negative	Positive
Urea	1000	Negative	Positive

Compound	Tested Concentration (mg/dL)	Spiked Oxazepam Level	
		Low Control -25% of cutoff (150 ng/mL)	**High Control** +25% of cutoff (250 ng/mL)
pH			
pH	3.0	Negative	Positive
pH	4.0	Negative	Positive
pH	5.0	Negative	Positive
pH	6.0	Negative	Positive
pH	7.0	Negative	Positive
pH	8.0	Negative	Positive
pH	9.0	Negative	Positive
pH	10.0	Negative	Positive
pH	11.0	Negative	Positive

g) Specific Gravity

Drug free urine samples with specific gravity ranging in value within 1.000 to 1.030 were split and spiked with Oxazepam to a final concentration of either 150 ng/mL or 250ng/mL (the Low Control and High Control concentrations, respectively). These samples were then evaluated in both qualitative and semi-quantitative modes. The Controls were detected accurately, indicating that no interference was observed.

Specific Gravity	Spiked Oxazepam Level	
	Low Control	**High Control**
1.004	Negative	Positive
1.005	Negative	Positive
1.007	Negative	Positive
1.010	Negative	Positive
1.011	Negative	Positive
1.013	Negative	Positive
1.019	Negative	Positive
1.023	Negative	Positive
1.025	Negative	Positive
1.029	Negative	Positive

H. Conclusion

The information supports a determination of substantial equivalence between DRI Benzodiazepine Assay and the predicate device Benzodiazepine Enzyme Immunoassay (K930529)