December 9, 2019

Microgenics Corporation
Minoti Patel
Director, Regulatory Affairs
45600 Kato Road
Fremont, CA 94538

Re: K190968
Trade/Device Name: CEDIA™ Benzodiazepine Assay
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine Test System
Regulatory Class: Class II
Product Code: JXM
Dated: October 21, 2019
Received: October 22, 2019

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. 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/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 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 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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190968

Device Name
CEDIA™ Benzodiazepine Assay

Indications for Use *(Describe)*

The CEDIA™ Benzodiazepine Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of benzodiazepines in human urine at a cutoff concentration of 200 ng/mL.

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 consideration 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.

1. 510(k) Summary

k190968

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 Director, 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	CEDIA™ 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:	CEDIA™ DAU Benzodiazepine Assay
Predicate Device Manufacturer:	Microgenics Corp.
Predicate Device Premarket Notification #:	K962734

B. Date Summary Prepared

December 09, 2019

C. Description of Device

CEDIA™ technology uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments, Enzyme acceptor (EA) and Enzyme Donor (ED). These fragments spontaneously re-associate to form fully active enzyme that, in the assay format, cleaves a substrate. This generates a color change that can be measured spectrophotometrically.

The assay consists of buffers (1 and 2) and lyophilized reagents (1a and 2a). The components include sheep polyclonal anti-benzodiazepine antibody, recombinant microbial "enzyme donor" – benzodiazepine conjugate, "enzyme acceptor", chlorophenol red β-D-galactopyranoside, stabilizers and preservatives. Add β-glucuronidase enzyme to the reconstituted EA solution before using the assay. All specimens must be tested with β-glucuronidase enzyme. This enzyme will hydrolyze the glucuronidated metabolites of benzodiazepines in the samples, thereby enabling the detection of benzodiazepine glucuronides.

D. Intended Use

The CEDIA™ Benzodiazepine Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of benzodiazepines in human urine at a cutoff concentration of 200 ng/mL.

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 consideration 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:** CEDIA™ Benzodiazepine Assay	**Predicate Device:** CEDIA™ DAU Benzodiazepine (K962734)
Intended Use	The CEDIA™ Benzodiazepine Assay is a homogeneous enzyme immunoassay intended for the qualitative and/or semi-quantitative determination of benzodiazepines in human urine at a cutoff concentration of 200 ng/mL. 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 consideration 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.	Same
Operating Principle (Technology)	CEDIA™	Same

Characteristic	**Candidate Device:** CEDIA™ Benzodiazepine Assay	**Predicate Device:** CEDIA™ DAU Benzodiazepine (K962734)
Measured Analyte	Benzodiazepines and their metabolites	Same
Test Matrix	Urine	Same
Cutoff Levels	HS 200 ng/mL	Same
Methodology	Homogeneous Enzyme Immunoassay	Same
Reagents Form	EA and ED: Lyophilized (Reconstitution Required) EARB and EDRB liquid ready-to-use.	Same
Antibody	Sheep polyclonal antibodies	Same
Storage	2–8 °C until expiration date	Same
Principal Operator	Trained professionals	Same
Calibrator Analyte	Oxazepam	Nitrazepam

F. Test Principle

The CEDIA™ Benzodiazepine Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. This assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments, termed Enzyme Acceptor (EA) and Enzyme Donor (ED) spontaneously re-associate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

G. Summary of Supporting Data

1. Analytical Performance:

Performance is evaluated at the manufacturer's site on the Beckman Coulter 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 for both cutoffs are summarized in the tables below.

Qualitative and Semi-Quantitative Analysis

Spiked Concentration (ng/mL)	% of Cutoff (200 ng/mL)	Total Precision (n=80)		
		# of Determinants	Qualitative Immunoassay Results (Negative/Positive)	Semi-quantitative Immunoassay Results (Negative/Positive)
0	-100%	80	80/0	80/0
50	-75%	80	80/0	80/0
100	-50%	80	80/0	80/0
150	-25%	80	80/0	79/1
200	100%	80	6/74	1/79
250	+25%	80	0/80	0/80
300	+50%	80	0/80	0/80
350	+75%	80	0/80	0/80
400	+100%	80	0/80	0/80

b) **Spike Recovery**

The study was performed using 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 for both cutoffs are summarized in the tables 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

Replicates	150 ng/mL (n=20)	250 ng/mL (n=20)
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 upto 800 ng/mL assay range, drug free urine was spiked to 900 ng/mL level calibrator using Oxazepam and diluted with drug free urine to generate 8 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)	Average Recovery (%)	Range of Recovery %
1	0	0	N/A	95.2 – 107.8
2	100	107.8	107.8	
3	200	205.8	102.9	
4	300	289.4	96.5	
5	400	412.4	103.1	
6	500	517.2	103.4	
7	600	595.0	99.2	
8	700	666.2	95.2	
9	800	766.2	95.8	

d) **Method Comparison and Accuracy**

The method comparison study was performed in accordance with CLSI Guideline EP09-A3.

One hundred and twenty eight samples were treated with β-glucuronidase reagent prior to analysis by the CEDIA™ Benzodiazepine Assay in both qualitative and semi-quantitative modes. The results were compared to LC-MS/MS where samples were also treated with β-glucuronidase. The overall concordance between LC-MS/MS and CEDIA™ Benzodiazepine Assay is 97% in Qualitative mode and 96% in Semi-Quantitative mode for high sensitivity 200 ng/mL cutoff.

The qualitative and semi-quantitative results is summarized in the tables below.

Qualitative Mode Accuracy study with LC-MS/MS as reference method for high sensitivity 200 ng/mL cutoff

Candidate Device Results	< 50% of Cutoff concentration by LC-MS/MS (< 100 ng/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	4*[b]	13	55
Negative	54	2	0	0

Agreement among Positives: 68/68 = 100%
Agreement among Negative: 56/60 = 93%

Semi-Quantitative Mode Accuracy study with LC-MS/MS as reference method for high sensitivity 200 ng/mL cutoff

Candidate Device Results	< 50% of Cutoff concentration by LC-MS/MS (< 100 ng/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	4*[b]	13	55
Negative	54	2	0	0

Agreement among Positives: 67/68 = 99%
Agreement among Negative: 56/60 = 93%

***[b] Discordant sample results for high sensitivity 200 ng/mL cutoff**

Sample ID	Qualitative	Semi-Quantitative		LC-MS/MS	
	Negative/ Positive	**Observed Concentration (ng/mL)**	**Negative/ Positive**	**Total Benzodiazepine Parent Only (ng/mL)**	**Negative/ Positive**
CA160606-045[*1]	Positive	3168	Positive	111	Negative
CA170605-001[*1]	Positive	3723	Positive	171	Negative
CA160926-057[*1]	Positive	1441	Positive	199	Negative
CA180820-014[*2]	Positive	291	Positive	197	Negative

*1 These samples are discordant due to the presence of parent benzodiazepine and also benzodiazepine metabolites as follows: CA160606-045 contains 7-aminoclonazepam at 3155 ng/ml. CA170605-001 7-aminoclonazepam at 560 ng/mL. CA160926-057 contains 7-aminoclonazepam at 411 ng/mL and 13 ng/mL of α hydroxyprazolam.
*2 Sample CA180820-014 is borderline negative by LC-MS/MS at 197ng/ml compared to the 200 ng/ml cut-off.

e) Specificity

The cross-reactivity of benzodiazepine compounds 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 benzodiazepines and metabolites

Benzodiazepines and metabolites	Tested Concentration (ng/mL)	Cross-reactivity (%)
α-Hydroxyalprazolam	110	182
α-Hydroxytriazolam	140	143
Alprazolam	100	200
7-Aminoclonazepam	800	25
7-Aminoflunitrazepam	225	89
7-Aminonitrazepam	500	40
Bromazepam	300	67
Chlordiazepoxide	2000	10
Clobazam	450	44
Clonazepam	350	57
Clorazepate	100	200
Delorazepam	100	200
Demoxepam	1500	13
Desalkylflurazepam (Norfludiazepam)	110	182
Diazepam	80	250
Estazolam	115	174
Flunitrazepam	125	160
Flurazepam	70	286
Lorazepam	250	80
Lorazepam glucuronide	400	50
Lormetazepam	175	114
Medazepam	200	100
Nitrazepam	290	69
Nordiazepam (Desmethyldiazepam)	70	286
Oxazepam	200	100
Oxazepam glucuronide	350	57
Prazepam	140	143
Temazepam	130	154
Temazepam glucuronide	250	80
Triazolam	90	222

Structurally unrelated compounds were evaluated by adding each substance to Oxazepam spiked at 150 ng/mL (-25% of the 200 ng/mL cutoff concentration), 250 ng/mL (+25% of the 200 ng/mL 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)	Low Control (150 ng/mL)	High Control (250 ng/mL)
6-Acetyl Morphine	100,000	Negative	Positive
10,11 Dihydrocarbamazepine	100,000	Negative	Positive
11-nor-Δ9-THC-COOH	100,000	Negative	Positive
Acetaminophen	100,000	Negative	Positive
Acetylsalicylic Acid	100,000	Negative	Positive
Amitriptyline	75,000	Negative	Positive
Amoxicillin	100,000	Negative	Positive
Amphetamine	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
Cimetidine	100,000	Negative	Positive
Codeine	100,000	Negative	Positive
Desipramine	100,000	Negative	Positive
Dextromethorphan	100,000	Negative	Positive
Digoxin	100,000	Negative	Positive
Diphenhydramine	30,000	Negative	Positive
Enalapril	100,000	Negative	Positive
EDDP	100,000	Negative	Positive
EMDP	3,000	Negative	Positive
Fentanyl	100,000	Negative	Positive
Fluoxetine	75,000	Negative	Positive
Fluphenazine	75,000	Negative	Positive
Haloperidol	100,000	Negative	Positive
Heroin	100,000	Negative	Positive
Hydrocodone	100,000	Negative	Positive
Hydromorphone	100,000	Negative	Positive
Ibuprofen	100,000	Negative	Positive

Structurally Unrelated Compounds	Tested Concentration (ng/mL)	Low Control (150 ng/mL)	High Control (250 ng/mL)
Levorphanol	100,000	Negative	Positive
Levothyroxine	75,000	Negative	Positive
Meperidine	100,000	Negative	Positive
Methadone	75,000	Negative	Positive
Methamphetamine	100,000	Negative	Positive
Morphine	100,000	Negative	Positive
Morhpine-3β-D-glucuronide	100,000	Negative	Positive
Morhpine-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
Oxaprozin	5,000	Negative	Positive
Oxycodone	100,000	Negative	Positive
Oxymorphone	100,000	Negative	Positive
Perphenazine	30,000	Negative	Positive
Phencyclidine	90,000	Negative	Positive
Phenobarbital	100,000	Negative	Positive
Procyclidine	100,000	Negative	Positive
Propoxyphene	100,000	Negative	Positive
Ranitidine	100,000	Negative	Positive
Secobarbital	100,000	Negative	Positive
Sertraline	7,000	Negative	Positive
Sulpiride	100,000	Negative	Positive
Tapentadol	100,000	Negative	Positive
Thioridazine	100,000	Negative	Positive
Tramadol	100,000	Negative	Positive
Triprolidine	40,000	Negative	Positive
Verapamil	100,000	Negative	Positive
Zolpidem	40,000	Negative	Positive
Enalapril	100,000	Negative	Positive
Salicyluric Acid	100,000	Negative	Positive
Tolmetin	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, endogenous and

exogenous physiologic substances on recovery of Oxazepam using CEDIA™ Benzodiazepine Assay was assessed by spiking known compounds of potentially interfering substances into the Low Control, 150 ng/mL (-25% of the cutoff concentration of 200 ng/mL) and High Control, 250 ng/mL (+25% of the cutoff concentration of 200 ng/mL). 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 for 200 ng/mL

Compound	**Tested Concentration (mg/dL)**	**200 ng/mL cutoff**	
		Low Control (150 ng/mL)	**High Control (250 ng/mL)**
Acetaminophen	10	Negative	Positive
Acetone	500	Negative	Positive
Acetyl Salicylic Acid	10	Negative	Positive
Ascorbic Acid	150	Negative	Positive
Caffeine	5	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
Ibuprofen	10	Negative	Positive
Oxalic Acid	50	Negative	Positive
Riboflavin	3	Negative	Positive
Sodium Chloride	1000	Negative	Positive
Urea	1000	Negative	Positive
pH			
pH	3	Negative	Positive
pH	4	Negative	Positive
pH	5	Negative	Positive
pH	6	Negative	Positive
pH	7	Negative	Positive
pH	8	Negative	Positive
pH	9	Negative	Positive
pH	10	Negative	Positive
pH	11	Negative	Positive

g) Specific Gravity

Drug free urine samples with specific gravity ranging in value within 1.002 to 1.029 were split and spiked with Oxazepam to a final concentration of either 150 ng/mL or 225 ng/mL (the Low Control concentrations). 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 interference data for 200 ng/mL

Specific Gravity	200 ng/mL cutoff	
	Low Control (150 ng/mL)	High Control (250 ng/mL)
1.002	Negative	Positive
1.004	Negative	Positive
1.005	Negative	Positive
1.007	Negative	Positive
1.010	Negative	Positive
1.012	Negative	Positive
1.014	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 CEDIA™ Benzodiazepine Assay and the predicate device CEDIA™ DAU Benzodiazepine Assay (K962734)