January 27, 2022

Carolina Liquid Chemistries, Corp.
Philip Shugart
Chief Executive Officer
313 Gallimore Dairy Road
Greensboro, North Carolina 27409

Re: K213211
Trade/Device Name: Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: September 27, 2021
Received: September 29, 2021

Dear Philip Shugart:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k213211

Device Name
Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System

Indications for Use *(Describe)*
The Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System is intended for the qualitative determination of benzoylecgonine (cocaine metabolite) in human urine at a cutoff value of 300 ng/mL. The assay is designed for professional use with a Carolina Liquid Chemistries CLC6410 automated clinical chemistry analyzer. For in vitro diagnostic use only. The assay provides a rapid screening procedure for determining the presence of benzoylecgonine in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical considerations and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test 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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510(k) Summary

510(k)#: K213211

A) Device Information:

Sponsor/Company Name:	Carolina Liquid Chemistries, Corp. 313 Gallimore Dairy RD. Greensboro, NC 27409 Phone: 1-877-722-8910 Fax: 1-336-722-8910
Correspondent Contact Information:	Philip G Shugart CEO Email: pshugart@carolinachemistries.com Phone: 1-877-722-8910 Fax: 1-336-722-8910
Common Name of Device:	Enzyme Immunoassay Cocaine and Cocaine Metabolites
Trade Name of Device:	Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System.
Device Product Code, Classification, Classification Name & Panel	DIO, Class II, 21 CFR 862.3250 Opiate Test System 91-Toxicology

Predicate Device Information

Predicate Device:	Cocaine Metabolite Enzyme Immunoassay
Predicate Device Manufacturer:	Lin-Zhi International
Predicate Device Common	Cocaine Metabolite Enzyme Immunoassay
Predicate Device Premarket Notification #	K020763
Predicate Device Product Code, Classification, Classification Name & Panel	DIO, Class II, 21 CFR 862.3250 Opiate Test System 91-Toxicology

B) Device Description:

The Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System is a ready-to-use, liquid reagent homogeneous enzyme immunoassay for qualitatively determining the presence of cocaine metabolite (benzoylecgonine) in human urine. The assay uses specific antibody that can detect benzoylecgonine in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs. The assay is based on competition between benzoylecgonine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) and free drug from the urine sample, for a fixed amount of antibody. In the absence of free drug from the urine sample, the specific antibody binds to the drug labeled with G6PDH causing a decrease in enzyme activity. The G6PDH enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD+) to NADH.

C) Indications for Use:

The Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System is intended for the qualitative determination of benzoylecgonine (cocaine metabolite) in human urine at a cutoff value of 300 ng/mL. The assay is designed for professional use with a Carolina Liquid Chemistries CLC6410 automated clinical chemistry analyzer. For in vitro diagnostic use only. The assay provides a rapid screening procedure for determining the presence of benzoylecgonine in urine. The assay provides only a preliminary analytical result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS) is the preferred confirmatory method. Clinical considerations and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary test result is positive.

D) Predicate Product Comparison Chart:

Characteristic:	Candidate Device:	Predicate Device:
Device Identifier and Submitter	Carolina Liquid Chemistries Corporation Cocaine Metabolite Enzyme Immunoassay (COCM) Test System	Cocaine Metabolite Enzyme Immunoassay Lin-Zhi International, Inc (K020763)
Indication for Use	The Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) Test System is intended for the qualitative determination of benzoylecgonine (cocaine metabolite) in human urine at a cut off value of 300 ng/mL. The assay is designed for professional use on the CLC6410 automated clinical chemistry analyzer. For in vitro diagnostic use only.	The Lin-Zhi Cocaine Metabolite Enzyme Immunoassay is intended for the qualitative and semi-quantitative determination of benzoylecgonine (cocaine metabolite) in human urine at a cut off value of 300 ng/mL. The assay is designed for professional use on a number of automated clinical chemistry analyzer. For in vitro diagnostic use only.
Operating Principle Technology	The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6- phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent Enzyme Immunoassay	Same
Measurand Analyte	Cocaine Metabolite (benzoylecgonine)	Same
Test Matrix	Urine	Same
Methodology	Homogeneous Enzyme Immunoassay	Same
Reagent Form	Liquid Ready to Use	Same
Antibody	mouse monoclonal anti-benzoylecgonine antibody	Same
Storage Temp	2-8°C	Same
Principal Operator	Trained Professionals	Same
Calibrator Levels	2	Same
Reference Instrument	CLC6410	Syncron CX4CE

E) Test Principle:

The Cocaine Metabolite Enzyme Immunoassay is a homogeneous enzyme immunoassay ready-to-use liquid reagent. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6- phosphate dehydrogenase (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity. In the absence of drug in the sample, benzoylecgonine-labeled G6PDH conjugate is bound to the antibody, and

the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody binds the free drug; the unbound benzoylecgonine-labeled G6PDH then exhibits its maximal enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically at 340 nm.

F) Summary of Supporting Data:

Analytical Performance

a. **Precision**- Precision was determined by spiking benzoylecgonine into drug free urine at the following concentrations (0, -75%, -50%, -25%, cutoff (300 ng/mL), +125%, +150%, +175% and 200%). Testing for within run was performed by running two replicates of each sample twice in one day. The between run was performed by running two replicates of each sample twice a day for 22 non-consecutive days. All sample concentrations were verified by a confirmatory method (LCMS). The results for the 300 ng/mL cutoff are summarized in the table below:

Within Run			
% Cutoff	Concentration	N	Neg/Pos
0%	0	4	4/0
-75%	75	4	4/0
-50%	150	4	4/0
-25%	225	4	4/0
Cutoff	300	4	3/1
125%	375	4	0/4
150%	450	4	0/4
175%	525	4	0/4
200%	600	4	0/4
	Run-to-Run		
% Cutoff	Concentration	N	Neg/Pos
0%	0	88	88/0
-75%	75	88	88/0
-50%	150	88	88/0
-25%	225	88	88/0
Cutoff	300	88	53/35
125%	375	88	0/88
150%	450	88	0/88
175%	525	88	0/88
200%	600	88	0/88

b. **Specificity**- Specificity of the assay is supported by cross reactivity studies that supported the predicate device, k020763

c. **Interference Testing**-

1) **The Effect of pH:** To investigate the effect of urine pH, negative human urine samples was divided into nine pools. Those pools were adjusted using sodium hydroxide (NaOH) and/or hydrochloric acid (HCL) to various pH conditions. After the pools were adjusted for pH, they were measured and the actual pH of each recorded. They were then divided in half so that there were two at each pH

level. Each half was then spiked with benzoylecgonine: one to 225 ng/mL and the other to 375 ng/mL (±25% of the 300 ng/mL cutoff). These 18-real human urine samples were then tested using the COCM Reagent Kit and results recorded in a table formatted similarly below.

Interfering Substances-		Actual pH	Test Result-		Actual pH	Test Result-
pH	pH Target		225ng/mL Target	pH Target		375ng/mL Target
	3	3.1	Neg	3	3.1	Pos
	4	4	Neg	4	3.9	Pos
	5	4.9	Neg	5	5.1	Pos
	6	6.1	Neg	6	6	Pos
	7	6.9	Neg	7	6.8	Pos
	8	8	Neg	8	8	Pos
	9	8.8	Neg	9	9.1	Pos
	10	10.1	Neg	10	10	Pos
	11	11	Neg	11	11.1	Pos

2) **The Effect of Specific Gravity:** To investigate the effect of urine specific gravity, negative human urine samples were divided into ten pools. These pools were adjusted using DI water and sodium chloride to the following target specific gravity conditions. After the pools were adjusted for specific gravity, they were measured, and the actual specific gravity was recorded. Each pool was then divided in half so there were two at each level of specific gravity. Each half was then spiked with benzoylecgonine: one to 225 ng/mL and the other to 375 ng/mL ±25% of the 300 ng/mL cutoff). Those 20-real human urine samples were then tested using the COCM Reagent Kit. The results were recorded in the table below.

Interfering Substances			Test Result			Test Result
SG	SG Target	Actual SG	225ng/mL Target	SG Target	Actual SG	375ng/mL Target
	1.000	1.000	Neg	1.000	1.001	Pos
	1.003	1.002	Neg	1.003	1.004	Pos
	1.007	1.007	Neg	1.007	1.008	Pos
	1.011	1.010	Neg	1.011	1.010	Pos
	1.012	1.013	Neg	1.012	1.013	Pos
	1.017	1.017	Neg	1.017	1.017	Pos
	1.018	1.019	Neg	1.018	1.019	Pos
	1.021	1.021	Neg	1.021	1.021	Pos
	1.024	1.025	Neg	1.024	1.025	Pos
	1.028	1.029	Neg	1.028	1.028	Pos

No Substantial Interference was noted.

d. **Carryover Testing- T**o determine carryover 21 samples, 10 "High" samples were spiked with benzoylecgonine at (1000 ng/mL) and 11 "Low" (0 ng/mL). They were assayed in the following order:

Carryover	Sample 1 (0)	Neg	Sample 8 (1000)	Pos	Sample 15 (0)	Neg
	Sample 2 (0)	Neg	Sample 9 (0)	Neg	Sample 16 (1000)	Pos
	Sample 3 (0)	Neg	Sample 10 (0)	Neg	Sample 17 (1000)	Pos
	Sample 4 (1000)	Pos	Sample 11 (0)	Neg	Sample 18 (0)	Neg
	Sample 5 (1000)	Pos	Sample 12 (0)	Neg	Sample 19 (1000)	Pos
	Sample 6 (0)	Neg	Sample 13 (1000)	Pos	Sample 20 (1000)	Pos
	Sample 7 (1000)	Pos	Sample 14 (1000)	Pos	Sample 21 (0)	Neg

No Carryover was noted during testing.

e. **Method Comparison and Accuracy**- Using 81 samples across the range of the assay should be tested according to the following distribution:

- 41 LC/MS Confirmed Negative Samples
  - 20 drug-free samples.
  - Remaining 21 samples between 0 ng/mL to 300 ng/mL.
    - 8 of the above 21 negative samples were within -50% of cutoff (150 ng/mL to 300 ng/mL)
- 40 LC/MS Confirmed Positives Samples
  - At least 8 samples within +50% of cutoff (300 ng/mL to 450 ng/mL)
  - All remaining samples greater than 300 ng/mL

Qualitative Mode Accuracy study with LC-MS/MS as reference method for 300 ng/mL cutoff shown below:

Results N=81 Cutoff=300ng/mL	**Drug Free** 0 ng/mL	**Low Negative** <50% off Cutoff (150ng/mL)	**Near Cutoff Negative** Between 50% and 99% of Cutoff (150-299 ng/mL)	**Near Cutoff Positive** Between 100% and 150% of Cutoff (300-450 ng/mL)	**High Positive** >150% of Cutoff (>450 ng/mL)	% Agreement
Positive				8	32	100%
Negative	20	11	10			100%

Agreement among positives: 100% /Agreement among negatives: 100%

No discordant samples were identified

Conclusion:

The Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) was evaluated for several performance characteristics, including precision, sensitivity, accuracy, analytical recovery, specificity, carryover, and interference. All studies show acceptable results when compared to the predicate device.

In conclusion, the Carolina Liquid Chemistries Cocaine and Cocaine Metabolite Enzyme Immunoassay (COCM) is substantially equivalent to the predicate.