K14/532

510(k) SUMMARY

JUL 14 2014

1. Date: July 11, 2014

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,
Guangzhou, P.R. China 510663

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: CR^3 Keyless Split Sample Cup Amphetamine-Cocaine

Classification:

Product Code	CFR #
DKZ	21CFR 862.3100
DIO	21CFR 862.3250

5. Predicate Devices: k130665
Wondfo Multi-Drug Urine Test Cup
Wondfo Multi-Drug Urine Test Panel

6. Intended Use
CR3 Keyless Split Sample Cup Amphetamine-Cocaine is a rapid test for the qualitative detection of d-Amphetamine (major metabolite of Amphetamine) and Benzoylecgonine (major metabolite of Cocaine) in human urine at a cutoff concentration of 1000ng/mL and 300ng/mL, respectively.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

7. Device Description

The CR3 Keyless Split Sample Cup Amphetamine-Cocaine test uses immunochromatographic assays for amphetamine and cocaine. The test is a lateral flow, one step system for the qualitative detection of d-Amphetamine (major metabolite of Amphetamine) and Benzoylecgonine (major metabolite of Cocaine) in human urine.

8. Substantial Equivalence Information

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of Amphetamine and Cocaine in human urine	Same, but also detects other drugs in human urine
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Amphetamine: 1000ng/ml Cocaine: 300ng/ml	Same for Amphetamine and Cocaine
Configurations	Cup	Cup, Panel
Conditions for Use	Over-the-Counter & Prescription Use	Same

9. Test Principle

The CR3 Keyless Split Sample Cup Amphetamine-Cocaine test is a rapid test for the qualitative detection of d-Amphetamine and benzoylecgonine in urine samples and contains lateral flow chromatographic immunoassays for amphetamine and cocaine. Each assay uses a mouse monoclonal anti-drug antibody-dye conjugate, fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibodies coated on the test membranes. When the absorbent end of the test is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the target cut-off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cut-off, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially

positive result. A band should form in the control region (C) of the device regardless of the presence of drug or metabolite in the sample.

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, at the cut-off, +25% cut-off, +50% cut-off , +75% cut-off and +100% cut-off. For each concentration, tests were performed two runs per day for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Amphetamine (AMP) testing

Result / AMP	-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
W11710501CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W11710502CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11710503CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Cocaine (COC) testing

Result / COC	-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
W11710501CU5	50-/0+	50-/0+	50-/0+	50-/0+	41+/9-	50+/0-	50+/0-	50+/0-	50+/0-
W11710502CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11710503CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-

        b. Linearity

Not applicable.

        c. Stability

The CR3 Keyless Split Sample Cup Amphetamine-Cocaine is stable at 4-30°C for 18 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 125 amphetamine samples and 125 cocaine samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs were labeled by a person who prepared them and would not participate in the sample testing. These samples were tested using three different lots by three different operators. Results were all positive at +25% and +50% cut-off and all negative at -25% and -50% cut-off for both cocaine and amphetamine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	d-Amphetamine	1000
Cocaine(COC)	Benzoylecgonine	300

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and to urine containing target drugs (d-amphetamine or benzoylecgonine) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of the CR3Keyless Split Sample Cup Amphetamine-Cocaine by three different operators. Compounds that showed no interference at a concentration of 100μg/mL are summarized below:

d-Amphetamine

4-Acetamidophenol	(-) Y Ephedrine	Penicillin-G
Acetophenetidin	Erythromycin	Pentazocaine
N-Acetylprocainamide	β-Estradiol	Pentobarbital
Acetylsalicylic acid	Estrone-3-sulfate	Perphenazine
Aminopyrine	Ethyl-p-aminobenzoate	Phencyclidine
Amitryptyline	Fenfluramine	Phenelzine
Amobarbital	Fenoprofen	Phendimetrazine
Amoxicillin	Furosemide	Phenobarbital
Ampicillin	Gentisic acid	Phetoin
Ascorbic acid	Hemoglobin	L-Phenylephrine
Apomorphine	Hydralazine	β-Phenylethlamine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine	Hydrocodone	Prednisolone
Benzilic acid	Hydrocortisone	Prednisone
Benzoic acid	O-Hydroxyhippuric acid	Procaine
Benzoylecgonine	3-Hydroxytyramine	Promazine
Bilirubin	Ibuprofen	Promethazine
Brompheniramine	Imipramine	D,L-Propanolol
Caffeine	(-) Isoproterenol	Propiomazine
Cannabidiol	Isoxsuprine	D-Propoxyphene

Cannabinol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine
hydrochloride
Ecgonine methylester
(IR,2S)-(-)-Ephedrine
L-Ephedrine

Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Meperidine
Meprobamate
Methadone
Methylphenidate
Morphine-3-Dglucuronide
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid

Oxycodone
Oxymetazoline
Papaverine

Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone
Tetrahydrozoline
Δ9-THC-COOH
Thebaine
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tyrosine
Uric acid

Verapamil
Zomepirac

Benzoylecgonine

Acetominophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic acid
DL-Amphetamine Sulfate
Apomorphine
Aspartame
Atropine
Benzilic acid

Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxymethamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine

Papaverine
Penicillin-G
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine

Benzoic acid	Iproniazid	Promethazine
Benzphetamine	(±) - Isoproterenol	DL-Propranolol
Bilirubin	Isoxsuprine	D-Propoxyphene
(±) -Brompheniramine	Ketamine	D-Pseudoephedrine
Caffeine	Ketoprofen	Quinidine
Cannabidiol	Labetalol	Quinine
Cannabinol	Levorphanol	Ranitidine
Chloralhydrate	Loperamide	Salicylic acid
Chloramphenicol	Maprotiline	Secobarbital
Chlordiazepoxide	Meperidine	Serotonin
Chlorothiazide	Meprobamate	Sulfamethazine
(±) -Chlorpheniramine	Methadone	Sulindac
Chlorpromazine	Methoxyphenamine	Temazepam
Chlorquine	(±) -3,4-Methylene dioxyamphetamine hydrochloride	Tetracycline
Cholesterol	(±)-3,4-Methylene-dioxymethamphetamine hydrochloride	Tetrahydrocortisone, 3-Acetate
Clomipramine	Morphine-3-β-D glucuronide	Tetrahydrocortisone 3-(β-D glucuronide)
Clonidine	Morphine Sulfate	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naloxone	Thiamine
(-) Cotinine	Naltrexone	Thioridazine
Creatinine	Naproxen	DL-Tyrosine
Deoxycorticosterone	Niacinamide	Tolbutamide
Dextromethorphan	Nifedipine	Triamterene
Diazepam	Norcodein	Trifluoperazine
Diclofenac	Norethindrone	Trimethoprim
Diflunisal	D-Norpropoxyphene	Trimipramine
Digoxin	Noscapine	Tryptamine
Diphenhydramine	DL-Octopamine	DL-Tryptophan
Doxylamine	Oxalic acid	Tyramine
Ecgonine methylester	Oxazepam	Uric acid
(-) - Ψ-Ephedrine	Oxolinic acid	Verapamil
Erythromycin	Oxycodone	Zomepirac
β-Estradiol	Oxymetazoline	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug (d-Amphetamine or Benzoylecgonine), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the CR3Keyless Split Sample Cup Amphetamine-Cocaine by three different operators. The drug metabolites and other components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables.

AMP (Amphetamine) (d-Amphetamine, Cut-off=1000 ng/mL)	Result	% Cross-Reactivity
d-Amphetamine	Positive at 1,000 ng/mL	100%
l-Amphetamine	Positive at 50,000 ng/mL	2%
d,l-Amphetamine	Positive at 3,000 ng/mL	33%
(+/-) 3,4-methylenedioxyamphetamine (MDA)	Positive at 5,000 ng/mL	20%
Phentermine	Positive at 3,000 ng/mL	33%
d-Methamphetamine	>100,000 ng/mL	<1%
l-Methamphetamine	>100,000 ng/mL	<1%
Ephedrine	>100,000 ng/mL	<1%
3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000 ng/mL	<1%

COC(Cocaine) (Benzoylecgonine, Cut-off=300 ng/mL)	Result	% Cross-Reactivity
Benzoylecgonine	Positive at 300 ng/mL	100%
Cocaine HCl	Positive at 750 ng/mL	40%
Cocaethylene	Positive at 12,500 ng/mL	2.4%
Ecgonine	Positive at 32,000 ng/mL	<1%

g. Effect of Urinary Density and pH

Twelve urine samples of normal, high, and low specific density ranges (1.000 to 1.035) were collected and spiked with either d-Amphetamine or benzoylecgonine at 25% below and 25% above the corresponding cut-off level. These samples were tested using three batches of the CR3Keyless Split Sample Cup Amphetamine-Cocaine by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with d-Amphetamine or benzoylecgonine at 25% below and 25% above the corresponding cut-off levels. These samples were tested using three batches of the CR3Keyless Split Sample Cup Amphetamine-Cocaine by three different operators.

The device performance was found not affected by varying urine density and pH.

2. Comparison Studies

The method comparison for the CR[3] Keyless Split Sample Cup Amphetamine-Cocaine was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results are compared to GC/MS results. The results are presented in the table below:

Amphetamine

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	3	17	20
	Negative	10	18	9	3	0
Viewer B	Positive	0	0	4	15	20
	Negative	10	18	8	5	0
Viewer C	Positive	0	0	3	16	20
	Negative	10	18	9	4	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	AMPC1035	811	positive
Viewer A	AMPC1062	945	positive
Viewer A	AMPC1065	987	positive
Viewer A	AMPC1061	1033	negative
Viewer A	AMPC1063	1002	negative
Viewer A	AMPC1064	1014	negative
Viewer B	AMPC1032	781	positive
Viewer B	AMPC1035	811	positive
Viewer B	AMPC1062	945	positive
Viewer B	AMPC1065	987	positive
Viewer B	AMPC1061	1033	negative
Viewer B	AMPC1063	1002	negative
Viewer B	AMPC1064	1014	negative
Viewer B	AMPC1092	1185	negative
Viewer B	AMPC1094	1312	negative
Viewer C	AMPC1033	702	positive
Viewer C	AMPC1035	811	positive
Viewer C	AMPC1065	987	positive
Viewer C	AMPC1061	1033	negative

Viewer C	AMPC1063	1002	negative
Viewer C	AMPC1091	1212	negative
Viewer C	AMPC1093	1296	negative

Cocaine

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	4	16	20
	Negative	10	15	11	4	0
Viewer B	Positive	0	0	4	17	20
	Negative	10	15	11	3	0
Viewer C	Positive	0	0	4	15	20
	Negative	10	15	11	5	0

Discordant table:

Viewer	Sample number	GC/MS result	viewer results
Viewer A	COCC1031	231	positive
Viewer A	COCC1033	229	positive
Viewer A	COCC1034	232	positive
Viewer A	COCC1062	293	positive
Viewer A	COCC1061	302	negative
Viewer A	COCC1064	314	negative
Viewer A	COCC1065	306	negative
Viewer A	COCC1091	351	negative
Viewer B	COCC1031	231	positive
Viewer B	COCC1032	219	positive
Viewer B	COCC1035	221	positive
Viewer B	COCC1062	293	positive
Viewer B	COCC1061	302	negative
Viewer B	COCC1063	325	negative
Viewer B	COCC1065	306	negative
Viewer C	COCC1032	219	positive
Viewer C	COCC1033	229	positive
Viewer C	COCC1034	232	positive
Viewer C	COCC1062	293	positive
Viewer C	COCC1061	302	negative
Viewer C	COCC1063	325	negative
Viewer C	COCC1064	314	negative
Viewer C	COCC1065	306	negative
Viewer C	COCC1095	378	negative

Lay-user study

A lay user study was performed at three intended user sites with 260 lay persons, of which, 20 tested for drug-free samples, 120 for d-Amphetamine samples, 120 for benzoylecgonine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/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:

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
d-Amphetamine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	16	4	80%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Benzoylecgonine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	4	16	80%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

Data analysis shows that all lay persons have carried out the test correctly and the results show good accuracy compared to theGC/MS. Also, a Flesch-Kincaid reading analysis was performed on both drug's package inserts (AMP and COC) and the score revealed a reading grade level of less than 7.

3. Clinical Studies

Not applicable

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that CR^3 Keyless Split Sample Cup Amphetamine-Cocaine is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 14, 2014

GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
LSI INTERNATIONAL INC
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20878

Re: K141532
Trade/Device Name: CR³ Keyless Split Sample Cup Amphetamine-Cocaine
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DIO
Dated: June 6, 2014
Received: June 10, 2014

Dear Mr. Shia:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k141532

Device Name
CR3 Keyless Split Sample Cup Amphetamine-Cocaine

Indications for Use *(Describe)*

CR3 Keyless Split Sample Cup Amphetamine-Cocaine is a rapid test for the qualitative detection of d-Amphetamine (major metabolite of Amphetamine) and Benzoylecgonine (major metabolite of Cocaine) in human urine at a cutoff concentration of 1000ng/mL and 300ng/mL, respectively.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Denise Johnson-Iyles -S

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