July 29, 2019

Immunalysis Corporation
Wenying (Jessica) Zhu
Senior Regulatory Affairs Specialist
829 Towne Center Drive
Pomona, CA 91767

Re: K183048
Trade/Device Name: Quantisal II Oral Fluid Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: PJD
Dated: June 17, 2019
Received: June 18, 2019

Dear Wenying (Jessica) Zhu:

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,

Kellie B. Kelm, Ph.D.
Acting 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)*
k183048

Device Name
Immunalysis Quantisal™ II Oral Fluid Collection Device

Indications for Use *(Describe)*
The Quantisal II Oral Fluid Collection Device is intended for the collection, preservation and transport of oral fluid specimens for tetrahydrocannabinol (THC), benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, benzodiazepines and tramadol. This device is for prescription 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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510(k) SUMMARY

A. GENERAL INFORMATION

Applicant Name:	Immunalysis Corporation 829 Towne Center Drive Pomona, CA 91767 Establishment # 2020952
Company Contact:	Wenying (Jessica) Zhu Manager, Regulatory Affairs Phone: (909) 451-6697 Email: wzhu@immunalysis.com
Date Prepared:	July 24, 2019

B. DEVICE IDENTIFICATION

Trade or Proprietary Names:	Immunalysis Quantisal™ II Oral Fluid Collection Device
Common Name:	Oral Fluid Collection Device

C. REGULATORY INFORMATION

Device Classification Name:	Oral Fluid Drugs Of Abuse And Alcohol Test Specimen Collection Device
Product Codes:	PJD
Regulatory Class:	Class II
Classification Regulation:	862.1675
Panel:	Clinical Chemistry (75)
Predicate Device:	Saliva Sampler [K942435]

D. DEVICE DESCRIPTION

The Quantisal II Oral Fluid Collection Device is intended for the collection, preservation and transport of oral fluid.

An oral fluid specimen is collected by placing two cellulose pads affixed to a polypropylene stem (Collector) under the tongue of an individual until a defined volume of saliva has saturated the cellulose pads. The defined volume taken up by the cellulose pads is indicated by coloration (blue) in a window on the stem (volume adequacy). The collector is then separated into two specific pads/stems and transferred into two separate polypropylene tubes (provided) both containing a specific volume of preservative buffer. The tubes are stoppered with provided caps. The specimens are then ready for storage or transport.

The design of two specific pads/stems allows for one aliquot to be used for screening and confirmation testing and the other aliquot to be stored as retain sample for potential second

chance testing.

The Quantisal II Oral Fluid Collection System collects 1 mL of neat oral fluid and dilutes it with 3 mL of preservative buffer. This results in a 1 to 4 dilution factor.

Immunalysis Quantisal II Oral Fluid Collection Device is sold as a stand-alone collection device.

E. INTENDED USE

The Quantisal II Oral Fluid Collection Device is intended for the collection, preservation and transport of oral fluid specimens for tetrahydrocannabinol (THC), benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, benzodiazepines and tramadol. This device is for prescription use only.

F. COMPARISON WITH PREDICATE

Attribute	Predicate Device Saliva Sampler [k942435]	Candidate Device Immunalysis Quantisal II Oral Fluid Collection Device
Similarities		
Intended Use	Collection and transport of oral fluid specimens for drug testing	Collection, preservation and transport of oral fluid specimens for drug testing
Material	Cellulose pad, polypropylene stem and transport tube	Same
Body Contact	Cellulose pad placed under the tongue for up to 10 mins	Same
Principle	Collecting an oral fluid specimen on a cellulose pad and preserving it in a buffer solution contained in a collection tube	Same
Sample Collection	Place cellulose pad under the tongue for collection until blue dye visible in the window of the stem	Same
Transport Tube	Polypropylene tube containing preservative buffer	Same
Sample Matrix	Human oral fluid	Same
Differences		
Collector	Collector containing one pad	Collector containing two pads. These two pads can be separated after collection
Sample Volume	1 mL	1 mL on each pad, 2 mL in total
Qty. of Transport Tube	1 transport tube	2 transport tubes, 1 for each pad

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial

equivalence of the Immunalysis Quantisal II Oral Fluid Collection Devices to the predicate device. Clinical and analytical performances were established using Liquid chromatography-tandem mass spectrometry (LC-MS/MS) and Gas chromatography–mass spectrometry (GC-MS).

1. Sample Volume

Fifty oral fluid samples were collected using Quantisal II collectors (collection pad with plastic stem) from fifty volunteers. Prior to collection, each collector (A and B) was weighed. After the volume adequacy indicator turned blue on both A and B collector stems, each collector was weighed again. The difference in weight was noted. Specific gravity of saliva was rounded to 1.000 to compute the volume collection. The results confirmed consistency of sample volume of 1 mL collected by each of Quantisal II collectors, and the volume difference between collector A and B doesn't exceed 15%.

Additional seventy-five oral fluid samples from known drug users were collected using Quantisal II collector. After the volume adequacy indicator turned blue on both A and B collector stems, each collector was weighed and compared to the average weight of collector before collection. The difference in weight was noted. Specific gravity of saliva was rounded to 1.000 to compute the volume collection.

2. Sample Collection Time

Fifty oral fluid samples from volunteers and seventy-five oral fluid samples from known drug users were collected using Quantisal II collector (collection pad with plastic stem). The collection time was documented. The results verified the sample collection time for Quantisal II Oral Fluid Collection Device is within the claimed time of 10 minutes in over 99% of subjects.

3. Drug Recovery

Drug free negative oral fluid spiked with the drug listed in **Table 1** at ±25%, +50% of the concentrations also listed in the table were collected and stored in Quantisal II Oral Fluid Collection Device overnight at room temperature. LC-MS/MS or GC-MS testing was performed the next day to determine percentage recovery. The studies demonstrated the Quantisal II Collection Device recovers tested drugs at greater than 80% of the original concentration.

Table 1. Drug Information

Drugs	Testing Method	Concentration (ng/mL)
THC	GC-MS	4
Benzoylecgonine	LC-MS/MS	15
Cocaine	LC-MS/MS	15
Morphine	LC-MS/MS	30
Codeine	LC-MS/MS	30
Oxycodone	LC-MS/MS	30
Hydrocodone	LC-MS/MS	30
6-acetylmorphine	LC-MS/MS	4
Phencyclidine	LC-MS/MS	10

Drugs	Testing Method	Concentration (ng/mL)
Amphetamine	LC-MS/MS	50
Methamphetamine	LC-MS/MS	50
Buprenorphine*	LC-MS/MS	3
Methadone*	LC-MS/MS	20
Nordiazepam*	LC-MS/MS	5
Tramadol*	GC-MS	50

4. Oral Fluid Sample Extraction Efficiency and Stability

Drug free negative oral fluid spiked with drugs listed in **Table 1** at +50% of the concentration listed in the table were collected and stored in Quantisal II Oral Fluid Collection Device and tested by LC-MS/MS or GC/MS at each time point at 25°C during the first 24 hours post-collection to determine the point at which extraction was complete and used as a baseline for comparison for determining sample stability. The drug recovery was >80% at 4 hours post collection for all drugs and reached >90% at 24 hours for all drugs to show a complete extraction.

Sample Stability testing was performed using LC-MS/MS or GC/MS at multiple timepoints post-collection at 25°C and at 2°C - 8°C. The results are presented in **Table 2**. The refrigerated study is still ongoing.

Table 2. Oral Fluid Sample Stability Results

Drugs	Stability at 8-25°C	Stability at 2-8°C
THC	10 days	10 days
Benzoylecgonine	10 days	10 days
Cocaine	5 days	10 days
Morphine	10 days	10 days
Codeine	10 days	10 days
Oxycodone	10 days	10 days
Hydrocodone	10 days	10 days
6-acetylmorphine	10 days	10 days
Phencyclidine	10 days	10 days
Amphetamine	10 days	10 days
Methamphetamine	10 days	10 days
Buprenorphine	10 days	10 days
Methadone	10 days	10 days
Benzodiazepines	10 days	10 days
Tramadol	10 days	10 days

Additional stability testing was performed on Quantisal II B specimens to verify oral fluid samples containing tested drugs stored in Quantisal II are stable after refrigerated storage. Stability results indicated that the Quantisal II “B” specimen retained for a “split specimen re-

confirmation test" were within 100+/- 10% recovery 1 months storage at 2°C - 8°C.

Table 3. Drug Information

Drugs	Testing Method	Concentration (ng/mL)
THC	GC-MS	2
Benzoylecgonine	LC-MS/MS	8
Cocaine	LC-MS/MS	8
Morphine	LC-MS/MS	15
Codeine	LC-MS/MS	15
Oxycodone	LC-MS/MS	15
Hydrocodone	LC-MS/MS	15
6-acetylmorphine	LC-MS/MS	2
Phencyclidine	LC-MS/MS	2
Amphetamine	LC-MS/MS	15
Methamphetamine	LC-MS/MS	15
Buprenorphine*	LC-MS/MS	3
Methadone*	LC-MS/MS	20
Benzodiazepines*	LC-MS/MS	5
Tramadol*	GC-MS	50

5. Sample Transportation Stability

Drug free negative oral fluid spiked with drugs listed in **Table 1** at ±50% of the concentration listed in the table were collected and stored in Quantisal II Oral Fluid Collection Device and packed in standard boxes used by common carrier (FedEx). During the 4-day (96 hours) simulated transportation study, the samples were stored in oven/freezer at temperatures ranged from -20°C to 40°C to encompass the temperatures likely to occur during shipment of products. The device used as the reference (unstressed) condition was stored continuously at the recommended storage condition at 2°C - 8°C. LC-MS/MS or GC/MS testing was performed in replicates of two and compared to the reference sample. The studies demonstrated the drug concentration of the sample collected by Quantisal II Oral Fluid Collection Device is within 20% of reference value during transportation.

6. Borosilicate Glass Vial Stability

Drug free expectorated oral fluid was spiked with the drug analyte at a concentration +50% of the concentrations listed in **Table 3**. The initial concentration of the solution was analyzed by mass spectrometry. Three borosilicate glass vials were introduced sequentially into each aliquot, stored at 25°C for 48 hours, and then tested using the same analytical method. The drug loss of the samples collected by borosilicate glass vial was within ±10% of the initial value after 48 hours storage at 25°C.

7. Clinical Specimens

At least forty deidentified, unaltered drug free clinical oral fluid samples and forty deidentified, unaltered clinical oral fluid samples containing drug for each drug class collected by expectoration (spitting) and Quantisal II Oral Fluid Collection Devices were obtained from clinical research facility, analyzed for drug listed in **Table 3** using LC-MS/MS or GC/MS. Quantisal II "A" and "B" results were compared to each other. The expectoration and Quantisal II results were compared against confirmation cutoffs listed in **Table 3**. A summary of the test results is presented in **Table 4**. The study demonstrated the accuracy between the two collectors of the Quantisal II Oral Fluid Collection Device when collecting clinical specimens. In no case was the expectorated neat oral fluid positive and the Quantisal II collected samples negative or vice versa. If drugs were present, they were present in samples from both oral fluid expectoration and device collection methods.

Table 4. Summary of Clinical Specimens Test Results

Drug Class	Drug	Sample Type	Number of Samples for Each Drug	Quantisal II A and B samples within ±15% of each other	Quantisal II A/B Agreement with Expectorated Samples
THC (40 drug-free 40 containing drug)	9-THC	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Cocaine and Cocaine Metabolites (80 drug-free 80 containing drug)	Benzoylecgonine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
	Cocaine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Opiates (200 drug-free 178 containing drug)	Morphine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
	Codeine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
	Oxycodone	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
	Hydrocodone	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	18	100% (18/18)	100% (18/18)
	6-AM	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
PCP (40 drug-free 40 containing drug)	PCP	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Amphetamine (40 drug-free 40 containing drug)	Amphetamine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Methamphetamine (40 drug-free 40 containing drug)	Methamphetamine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)

Drug Class	Drug	Sample Type	Number of Samples for Each Drug	Quantisal II A and B samples within ±15% of each other	Quantisal II A/B Agreement with Expectorated Samples
Buprenorphine (40 drug-free 40 containing drug)	Buprenorphine	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Methadone (40 drug-free 40 containing drug)	Methadone	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Benzodiazepines (40 drug-free 40 containing drug)	Nordiazepam	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)
Tramadol (40 drug-free 40 containing drug)	Tramadol	Drug-Free	40	100% (40/40)	100% (40/40)
		Containing drug	40	100% (40/40)	100% (40/40)

8. Expectorated Oral Fluid Samples Processed Through Quantisal II (Dipping Study)

At least sixty deidentified, unaltered drug containing oral fluid samples were collected by expectoration (spitting) at clinical research facility, and analyzed using LC-MS/MS or GC/MS. A minimum of ten samples of each drug were within ±50% of the confirmation cutoffs listed in **Table 3**. A Quantisal II device was introduced into each expectorated sample. The next day, Quantisal II samples A and B were analyzed by mass spectrometry. 899/900 paired results meet the criteria that Quantisal II A and B concentrations were within 15% of each other. 899/900 paired results meet the criteria that Quantisal II concentration was within ±20% of the expectoration result. This study demonstrated no difference in drug concentrations in oral fluid when expectorated samples are compared to the same oral fluid subjected to Quantisal II collection regardless of drug class. The Quantisal II oral fluid collection device does not introduce bias to quantitative and qualitative results of expectoration neat oral fluid sample (clinical truth).

H. CONCLUSION

The information provided in this pre-market notification demonstrates that the Immunalysis Quantisal II Oral Fluid Collection Device is substantially equivalent to the legally marketed predicate device for its intended use.