July 28, 2020

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

Re: K200801
Trade/Device Name: Quantisal™ 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 26, 2020
Received: June 30, 2020

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,

Marianela Perez-Torres, M.T., 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)*
k200801

Device Name
Quantisal™ Oral Fluid Collection Device

Indications for Use *(Describe)*
For In Vitro Diagnostic Use
The Quantisal Oral Fluid Collection Device is intended for the collection, preservation and transport of oral fluid specimens for tetrahydrocannabinol (THC), cocaine and its metabolite benzoylecgonine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, benzodiazepines and tramadol.

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 23, 2020

B. DEVICE IDENTIFICATION

Trade or Proprietary Names:	Quantisal™ 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:	Quantisal™ II Oral Fluid Collection Device [K183048]

D. DEVICE DESCRIPTION

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

An oral fluid specimen is collected by placing a cellulose pad affixed to a polypropylene stem (Collector) under the tongue of an individual until a defined volume of saliva has saturated the cellulose pad. 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 transferred into a provided polypropylene tube containing a specific volume of preservative buffer. The tube is stoppered with provided caps. The specimen is ready for storage or transport.

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

E. INTENDED USE

For *In Vitro* Diagnostic Use

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

F. COMPARISON WITH PREDICATE

Attribute	Predicate Device Quantisal II Oral Fluid Collection Device [k183048]	Candidate Device Quantisal Oral Fluid Collection Device
Similarities		
Intended Use	Collection, preservation and transport of oral fluid specimens for tetrahydrocannabinol (THC), cocaine and its metabolite benzoylecgonine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, benzodiazepines and tramadol. For prescription Use only.	Identical
Material	Cellulose pad, polypropylene stem and transport tube	Identical
Body Contact	Cellulose pad placed under the tongue for up to 10 mins	Identical
Principle	Collecting an oral fluid specimen on a cellulose pad and preserving it in a buffer solution contained in a collection tube	Identical
Sample Collection	Place cellulose pad under the tongue for collection until blue dye visible in the window of the stem	Identical
Transport Tube	Polypropylene tube containing preservative buffer	Identical
Sample Matrix	Human oral fluid	Identical
Differences		
Collector	Collector containing two pads. These two pads can be separated after collection	Collector containing one pad
Sample Volume	1 mL on each pad, 2 mL in total	1 mL

Attribute	Predicate Device Quantisal II Oral Fluid Collection Device [k183048]	Candidate Device Quantisal Oral Fluid Collection Device
Qty. of Transport Tube	2 transport tubes, 1 for each pad	1 transport tube

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial equivalence of the Immunalysis Quantisal 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

Seventy-five oral fluid samples from known drug users were collected using Quantisal collectors (collection pad with plastic stem). After the volume adequacy indicator turned blue on the collector stem, the 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. The results confirmed consistency of sample volume of 1 mL collected by the Quantisal collector.

2. Sample Collection Time

Seventy-five oral fluid samples from known drug users were collected using Quantisal collector (collection pad with plastic stem). The collection time was documented. The results verified the sample collection time for Quantisal Oral Fluid Collection Device is within the claimed time of 10 minutes in over 90% of subjects.

3. Drug Recovery

Drug free negative oral fluid spiked with the drug listed in **Table 1** at ±25%, +50% of the cutoff were collected and stored in Quantisal 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 Collection Device recovers tested drugs at greater than 80% of the original concentration.

Table 1. Drug Information

Drugs	Testing Method	SAMHSA Screening Cutoff (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

Drugs	Testing Method	SAMHSA Screening Cutoff (ng/mL)
Hydrocodone	LC-MS/MS	30
6-acetylmorphine	LC-MS/MS	4
Phencyclidine	LC-MS/MS	10
Amphetamine	LC-MS/MS	50
Methamphetamine	LC-MS/MS	50
Buprenorphine*	LC-MS/MS	3
Methadone*	LC-MS/MS	20
Benzodiazepines *	LC-MS/MS	5
Tramadol*	GC-MS	50

*Cutoff not established by SAMHSA. Buprenorphine cutoff is suggested by Brigham and Women's Hospital, Boston, MA. Methadone cutoff is determined by the reference article [1]. Benzodiazepines and Tramadol cutoffs are determined by referencing 2013-2014 National Roadside Study of Alcohol and Drug Use by Drivers.

4. Oral Fluid Sample Extraction Efficiency and Stability

Drug free negative oral fluid spiked with drugs listed in **Table 1** at +50% of the cutoff were collected and stored in Quantisal 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 met the minimum acceptance criterion of >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**.

Table 2. Oral Fluid Sample Stability Results

Drugs	Stability at 8-25°C	Stability at 2-8°C
THC	10 days	2 months
Benzoylecgonine	10 days	3 months
Cocaine	5 days	1 month
Morphine	10 days	3 months
Codeine	10 days	3 months
Oxycodone	10 days	3 months
Hydrocodone	10 days	3 months
6-acetylmorphine	10 days	3 months
Phencyclidine	10 days	3 months
Amphetamine	10 days	3 months
Methamphetamine	10 days	3 months
Buprenorphine	10 days	3 months
Methadone	10 days	3 months

[1] Teresa R. Gray, Riet Dams, Robin E. Choo, Hendree E. Jones, Marilyn A. Huestis, Methadone disposition in oral fluid during pharmacotherapy for opioid-dependence, Forensic Science International 206 (2011)98-102.

Drugs	Stability at 8-25°C	Stability at 2-8°C
Benzodiazepines	10 days	3 months
Tramadol	10 days	3 months

5. Sample Transportation Stability

Drug free negative oral fluid spiked with drugs listed in **Table 1** at ±50% of the cutoff were collected and stored in Quantisal 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. Additionally, a supplemental study was performed by testing samples collected by Quantisal device stored at three different temperature ranges for 24 hours respectively: 25°C, 40°C and 2°C-8°C. The studies demonstrated the drug concentration of the sample collected by Quantisal 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 confirmation cutoffs 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.

Table 3. Drug Information

Drugs	Testing Method	SAMHSA Confirmation Cutoff (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	10 (laboratory LOQ 5 ng/mL was used)
Amphetamine	LC-MS/MS	25 (15 ng/mL was used according to previously proposed SAMHSA cutoff)
Methamphetamine	LC-MS/MS	25 (15 ng/mL was used according to previously proposed SAMHSA cutoff)
Buprenorphine*	LC-MS/MS	3

Drugs	Testing Method	SAMHSA Confirmation Cutoff (ng/mL)
Methadone*	LC-MS/MS	20
Benzodiazepines*	LC-MS/MS	5
Tramadol*	GC-MS	50

*Cutoff not established by SAMHSA.

7. Expectorated Oral Fluid Samples Processed Through Quantisal (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 device was introduced into each expectorated sample. The next day, Quantisal samples were analyzed by mass spectrometry. 899/900 paired results meet the criteria that Quantisal concentration was within ±20% of the expectorated 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 collection regardless of drug class. The Quantisal oral fluid collection device does not introduce bias to quantitative and qualitative results of expectoration neat oral fluid sample (clinical truth).

8. Drug Free Clinical Specimens

At least forty deidentified, unaltered drug free clinical oral fluid samples collected by expectoration (spitting) and Quantisal Oral Fluid Collection Devices were obtained from clinical research facility, analyzed for drug listed in **Table 3** using LC-MS/MS or GC/MS. The results of all expectorated samples and Quantisal samples are negative for each drug. The study demonstrated the accuracy of the Quantisal Oral Fluid Collection Device when collecting drug free clinical specimens.

H. CONCLUSION

The information provided in this premarket notification demonstrates that the Immunalysis Quantisal Oral Fluid Collection Device is substantially equivalent to the legally marketed predicate device.