Immunalysis Corporation
Shubhajit Mitra
Regulatory Affairs Manager
829 Towne Center Drive
Pomona, California 91767

Re: K232898
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: September 18, 2023
Received: September 18, 2023

Dear Shubhajit Mitra:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2023.11.21 14:08:41 -05'00'

Josepk Kotarek, Ph.D.
Toxicology Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K232898

Device Name
Quantisal™ Oral Fluid Collection Device

Indications for Use *(Describe)*
The Quantisal™ Oral Fluid Collection Device is intended for the collection, preservation and transport of oral fluid specimens for drugs of abuse testing. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with 21 CFR Section 807.92.

510(k) number:	K232898
Submitter	
Applicant Name:	Immunalysis Corporation 829 Towne Center Drive Pomona, CA 91767
FDA Establishment #:	2020952
Primary Correspondent:	Shubhajit Mitra Regulatory Affairs Manager
Primary Phone:	508-330-4796
Primary Email:	shubhajit.mitra@abbott.com
Alternate Correspondent:	Iris Saliba Associate Director, Regulatory Affairs
Secondary Phone:	619-540-3931
Alternate Email:	iris.saliba@abbott.com
Date Prepared:	Nov 3, 2023

5.1 Device Information

Trade or Proprietary Names:	Quantisal™ Oral Fluid Collection Device
Common Name:	Quantisal™
Device Classification Name:	Oral Fluid Drugs of Abuse and Alcohol Test Specimen Collection Device
Product Codes:	PJD
Regulatory Class:	Class II
Classification Regulation:	21 CFR 862.1675
Panel:	Clinical Chemistry

Predicate Information

Company:	Immunalysis Corporation
Device:	Quantisal™ Oral Fluid Collection Device (K200801)

5.2 Device Description

The Quantisal™ Oral Fluid Collection Device is intended for the collection, preservation, and transport of oral fluid specimens for drugs of abuse testing. The device is for prescription use only.

An oral fluid specimen is collected by placing a cellulose pad affixed to a polypropylene stem 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 pad is indicated by coloration (blue) in a window on the stem (volume adequacy). The collector is then transferred into a polypropylene tube (provided) containing 3 mL of preservative buffer. The tube is stoppered with provided cap. The specimen is ready for storage and transport.

The Quantisal™ Oral Fluid Collection Device collects 1 mL of neat oral fluid and dilutes it with 3 mL of preservative buffer contained in the provided transport tube. This results in a 1 to 4 dilution factor.

5.3 Indication for Use

The Quantisal™ Oral Fluid Collection Device is intended for the collection, preservation, and transport of oral fluid specimens for drugs of abuse testing. This device is for prescription use only.

5.4 Comparison to Predicate Device

The subject device has the same design and functionality as the predicate device.

Table 5-1: Device Comparison

Device Characteristics	Subject Device - Quantisal™ Oral Fluid Collection Device	Predicate Device (K200801)
Similarities		
Manufacturer	Immunalysis Corporation	Identical
Proprietary Name	Quantisal™ Oral Fluid Collection Device	Identical
Classification Product Code	PJD	Identical
Device Class	II	Identical
Regulation Number	21 CFR 862.1675	Identical
Review Panel	Clinical Chemistry	Identical
Material	Cellulose pad, polypropylene stem, preservative buffer 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 is visible in the window of the stem	Identical
Transport Tube	Polypropylene tube containing preservative buffer	Identical
Sample Matrix	Human oral fluid	Identical
Collector	Collector containing a pad	Identical
Sample Volume	1 mL	Identical

Device Characteristics	Subject Device - Quantisal™ Oral Fluid Collection Device	Predicate Device (K200801)
Intended Use	Intended for use in the collection, preservation, and transport of oral fluid specimens for drugs of abuse testing	Identical
Differences		
Indication for Use	The Quantisal™ Oral Fluid Collection Device is intended for the collection, preservation, and transport of oral fluid specimens for drugs of abuse testing. This device is for prescription use only.	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. For prescription Use only.

5.5 Performance Characteristics

The subject and predicate device are similar except for the change in the indications for use and the extension of stability claims for some analytes. There is no change to the device design or functionality. The performance data submitted and cleared in K200801 was established using a representative group of analytes that supports the general intended use of the device. The representative drug analytes studied on Quantisal™ represent frequently abused drug classes and variable physicochemical properties. The representative drug analytes evaluated for performance of Quantisal™ Oral Fluid Collection Device are listed in **Table 5-2** below:

Table 5-2: Representative Drug Analytes

Representative Drugs	Cutoff Concentration (ng/mL) used for performance evaluation
THC	4
Benzoylecgonine	15
Cocaine	15
Morphine	30
Codeine	30

Representative Drugs	Cutoff Concentration (ng/mL) used for performance evaluation
Oxycodone	30
Hydrocodone	30
6-acetylmorphine	4
Phencyclidine	10
Amphetamine	50
Methamphetamine	50
Buprenorphine	3
Methadone	20
Benzodiazepines (Nordiazepam)	5
Tramadol	50

Clinical and analytical performance were established using Liquid chromatography-tandem mass spectrometry (LC-MS/MS) and Gas chromatography–mass spectrometry (GC-MS).

The representative drug analytes are not an inclusive list of targets that could be tested in specimens collected using Quantisal™. As per the Instructions for Use, use of this device for the collection, preservation, and transportation of oral fluid specimens for in vitro diagnostic drug of abuse testing for analytes not listed in Table 5-1must be validated prior to such use. The following performance studies were performed on the Quantisal™:

5.5.1 Sample Volume

The performance studies to verify the sample volume collected using Quantisal™ were submitted and cleared in K200801.

5.5.2 Sample Collection Time

The performance studies to verify the sample collection time were submitted and cleared in K200801.

5.5.3 Drug Recovery

Drug recovery studies performed on representative drug analytes using Quantisal™ Oral Fluid Collection Device were submitted and cleared in K200801.

5.5.5 Oral Fluid Sample Stability

The stability of the representative drugs in the oral fluid specimens collected with the Quantisal™ Oral Fluid Collection Device was evaluated with low positive samples (+50%) cutoff at room temperature (8-25°C) and refrigerated (2-8°C). Sample Stability testing was performed using LC-MS/MS or GC/MS at multiple timepoints post collection at 8°C - 25°C and at 2°C - 8°C. The stability results of the representative analytes from K200801 and refrigerated sample stability extension results in this submission are presented in Table 5-3.

Table 5-3: Oral Fluid Specimens Stability in the Quantisal™

Drugs	Initial Concentration (ng/mL)	Stability at 8-25°C	Stability at 2-8°C
THC	6.0	10 days	2 months
Benzoylecgonine	22	10 days	12 months
Cocaine	22	5 days	1 month
Morphine	45	10 days	12 months
Codeine	46	10 days	12 months
Oxycodone	47	10 days	12 months
Hydrocodone	46	10 days	12 months
6-acetylmorphine	5.8	10 days	12 months
Phencyclidine	14	10 days	12 months
Amphetamine	75	10 days	12 months
Methamphetamine	74	10 days	12 months

Drugs	Initial Concentration (ng/mL)	Stability at 8-25°C	Stability at 2-8°C
Buprenorphine	4.5	10 days	12 months
Methadone	29	10 days	12 months
Benzodiazepines	7.5	10 days	12 months
Tramadol	75	10 days	12 months

5.5.6 Sample Transportation Stability

Sample Transportation Stability performed on representative drug analytes using Quantisal™ Oral Fluid Collection Device was submitted and cleared in K200801.

5.5.7 Clinical Specimen Study

Clinical specimen testing performed on the representative analytes listed in Table 5-2 using Quantisal Oral Fluid Collection Device was submitted and cleared in K200801.

5.6 Substantial Equivalence

Quantisal™ Oral Fluid Collection Device is substantially equivalent to the predicate device. Both devices are intended to be used for collection, preservation, and transport of oral fluid for drug of abuse testing. Both devices have same design, materials and functionality. Both devices, using the same performance data set, have demonstrated safety and efficacy for the intended use regardless of the drug analyte tested.

5.7 Conclusion

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

intended use for collection, preservation, and transport of oral fluid for drug of abuse testing regardless of the analyte being tested.