July 28, 2023

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

Re: K223781
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 13, 2023
Received: June 14, 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 (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 -S

Marianela Perez-Torres, Ph.D.
Acting Director
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)*
K223781

Device Name
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 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: | K223781 |
| Submitter | |
| Applicant Name: | Immunalysis Corporation<br>829 Towne Center Drive<br>Pomona, CA 91767 |
| FDA Establishment #: | 2020952 |
| Primary Correspondent: | Shubhajit Mitra<br>Regulatory Affairs Manager |
| Primary Phone: | 508-330-4796 |
| Primary Email: | shubhajit.mitra@abbott.com |
| Alternate Correspondent: | Regina Xavier<br>Associate Director, Regulatory Affairs |
| Secondary Phone: | 630-596-6625 |
| Alternate Email: | regina.xavier@abbott.com |
| Date Prepared: | July 27, 2022 |

### 5.1 Device Information

| | |
|---|---|
| Trade or Proprietary Names: | Quantisal II Oral Fluid Collection Device |
| Common Name: | Quantisal II |
| 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 II Oral Fluid Collection Device (K183048) |

### 5.2 Device Description

The Quantisal II 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 split collector containing two cellulose pads 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 pads is indicated by coloration (blue) in a window on the stem (volume adequacy). The collector is then separated into two specific pads/stems (Collector 1 and 2) and transferred into two separate polypropylene tubes (provided) both containing 3 mL of preservative buffer (Labelled A and B). The tubes are stoppered with provided caps. The specimen is ready for storage and transport.

The design of the split collector allows for the simultaneous collection of 2 aliquots; one aliquot to be used for screening and confirmation testing and the other aliquot to be stored as retain sample for potential confirmation testing.

The Quantisal II 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 II 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 II Oral Fluid Collection Device | Predicate Device (K183048) |
|---|---|---|
| **Similarities** | | |
| Manufacturer | Immunalysis Corporation | Identical |
| Proprietary Name | Quantisal II 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 |

| Device Characteristics | Subject Device - Quantisal II Oral Fluid Collection Device | Predicate Device (K183048) |
|---|---|---|
| Collector | Split collector containing two pads and two stems. These two pads can be separated after collection into collector 1 and collector 2. | Identical |
| Sample Volume | 1 mL on each pad, 2 mL in total | Identical |
| 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 II 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 II 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 candidate and predicate device are identical 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 K183048 was established using a representative group of analytes that supports the general intended use of the device. The representative drug analytes studied on Quantisal II Oral Fluid Collection Device represent frequently abused drug classes and variable physicochemical properties. The representative drug analytes evaluated for performance of Quantisal II 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 |
| Oxycodone | 30 |
| Hydrocodone | 30 |
| 6-acetylmorphine | 4 |
| Phencyclidine | 10 |
| Amphetamine | 50 |
| Methamphetamine | 50 |
| Buprenorphine | 3 |
| Methadone | 20 |
| Nordiazepam | 5 |
| Tramadol | 50 |

Clinical and analytical performances 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 II Oral Fluid Collection Device. 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 5-2 should be validated prior to such use..

The following performance studies were performed on the Quantisal II Oral Fluid Collection Device:

### 5.5.1 Sample Volume

The performance studies to verify the sample volume collected using Quantisal II Oral Fluid Collection Device were submitted and cleared in K183048.

### 5.5.2 Sample Collection Time

The performance studies to verify the sample collection time were submitted and cleared in K183048.

### 5.5.3 Drug Recovery

Drug recovery studies performed on representative drug analytes using Quantisal II Oral Fluid Collection Device were submitted and cleared in K183048.

### 5.5.4 Borosilicate Glass Vial Stability

This study was performed to verify that the borosilicate glass vial used for collection of expectorated neat oral fluid sample does not affect the drug concentrations and has adequate analytical recovery to serve as the "analytical truth". The study results were submitted and cleared under K183048.

### 5.5.5 Oral Fluid Sample Stability

The stability of the representative drugs in the oral fluid specimens collected with the Quantisal II Oral Fluid Collection Device was evaluated with low positive samples (+50%) at room temperature (8-25°C) and refrigerated (2-8°C). The stability of drugs in oral fluid specimens was measured by comparing the concentration of the primary (A) specimen and the retained split (B) specimen over time to the initial concentration. Results within ±10% of the initial concentration are listed in **Table 5-3**. For all other drugs or drug analytes that are not included in the representative drugs identified in **Table 5-3**, it is recommended to establish sample stability before using Quantisal II Oral Fluid Collection Device for drug of abuse testing.

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

| Representative Drugs | Initial Concentration (ng/mL) | | A Specimen Stability (within ±10% of the initial conc.) | | B Specimen Stability (within ±10% of initial conc.) | |
|---|---|---|---|---|---|---|
| | Pad A | Pad B | 8-25°C | 2-8°C | 8-25°C | 2-8°C |
| THC | 5.9 | 5.9 | 10 days | 2 months | 10 days | 2 months |
| Benzoylecgonine | 21 | 22 | 10 days | 12 months | 10 days | 12 months |
| Cocaine | 22 | 22 | 5 days | 1 month | 5 days | 1 month |
| Morphine | 44 | 45 | 10 days | 12 months | 10 days | 12 months |
| Codeine | 46 | 47 | 10 days | 12 months | 10 days | 12 months |
| Oxycodone | 46 | 47 | 10 days | 12 months | 10 days | 12 months |
| Hydrocodone | 45 | 45 | 10 days | 12 months | 10 days | 12 months |
| 6-acetylmorphine | 6.0 | 6.0 | 10 days | 12 months | 10 days | 12 months |
| Phencyclidine | 14 | 14 | 10 days | 12 months | 10 days | 12 months |
| Amphetamine | 76 | 75 | 10 days | 12 months | 10 days | 12 months |
| Methamphetamine | 76 | 74 | 10 days | 12 months | 10 days | 12 months |
| Buprenorphine | 4.4 | 4.5 | 10 days | 12 months | 10 days | 12 months |
| Methadone | 30 | 30 | 10 days | 12 months | 10 days | 12 months |
| Nordiazepam | 7.4 | 7.3 | 10 days | 12 months | 10 days | 12 months |
| Tramadol | 73 | 75 | 10 days | 12 months | 10 days | 12 months |

### 5.5.6 Sample Transportation Stability

Sample Transportation Stability performed on representative drug analytes using Quantisal II Oral Fluid Collection Device was submitted and cleared in K183048.

### 5.5.7 Clinical Specimens

A study was conducted to demonstrate equivalency between the two collection pads of the Quantisal II Oral Fluid Collection Device and the results were submitted and cleared in K183048. At least forty deidentified, unaltered drug free clinical oral fluid samples and up to forty deidentified, unaltered clinical oral fluid samples containing representative drugs collected by expectoration (spitting) and Quantisal II Oral Fluid Collection Devices were obtained from a clinical research facility. These were analyzed for drugs listed in **Table 5-2** using LC-MS/MS or GC/MS. Quantisal II Tube "A" and "B" results were compared to each other. The results from the expectorated neat oral fluid and the Quantisal II Oral Fluid Collection Device collected samples

matched 100%. If representative drugs were present, they were present in samples from both oral fluid expectoration and Quantisal II Oral Fluid Collection Device.

### 5.5.8 Expectorated Oral Fluid Samples Processed Through Quantisal II (Dipping Study)

A study was conducted to verify that drug concentrations in oral fluid samples collected by Quantisal II Oral Fluid Collection Device are analytically comparable to the neat oral fluid samples collected by expectoration was submitted and cleared in K183048. The samples used in the study were collected from self-reported drug user patients at a clinical research facility. At least 60 oral fluid sample for each of the representative drug listed in **Table 5-2**. was collected by expectoration into a borosilicate glass vial. An aliquot of each sample was subsequently processed through the Quantisal II Oral Fluid Collection Device by dipping the collection pad into the oral fluid until the volume adequacy indicator turned blue. The expectoration samples and Quantisal II Oral Fluid Collection Device samples were assayed by LC-MS/MS or GC-MS. The results showed that the 899/900 Quantisal II Oral Fluid Collection Device samples had concentrations that were within ±20% of expectoration concentration.

## 5.6 Substantial Equivalence

Quantisal II 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 are identical in 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 II 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.