510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K232898

B Applicant

Immunalysis Corporation

C Proprietary and Established Names

Quantisal™ Oral Fluid Collection Device

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PJD	Class II	21 CFR 862.1675 - Blood Specimen Collection Device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to an existing device.

B Measurand:

Not applicable.

C Type of Test:

For the collection, preservation, and transport of oral fluid specimens with drugs of abuse testing.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The Quantisal Oral Fluid Collection Devices has been previously cleared for the measurement of THC, Benzoylecgonine, Cocaine, Morphine, Codeine, Oxycodone, Hydrocodone, 6-acetylmorphine, Phencyclidine, Amphetamine, Methamphetamine, Buprenorphine, Methadone, Benzodiazepines and Tramadol. Use of the device for the collection, preservation, and transport of any other analyte for drugs of abuse testing should be validated prior to such use.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A 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 Quantisal device is designed to collect 1 mL ± 10% oral fluid sample. Each device contains (a) cellulose pad affixed to a polypropylene stem and (b) one transportation tube.

B Principle of Operation:

The Quantisal device is designed to collect 1 mL ± 10% oral fluid sample. Each device contains a collector made up of a cellulose pad with cellulose extending into the interior of a polypropylene stem. Blue dye is pre-applied to the cellulose inside the stem. When the cellulose pad is placed under the tongue of a donor, oral fluid is collected via passive diffusion. Upon saturating the cellulose pad, oral fluid migrates along the cellulose tail through capillary action and dissolves the dye. As oral fluid collection continues, the dye becomes visible in the window on the stem. Specimen collection is complete when the window is completely blue. The collector is then removed from the mouth. The pad is transferred into provided polypropylene transport tube which contains 3 mL of preservative buffer. The preservative buffer serves as a reservoir into which analytes may distribute, permitting recovery of analytes from the pad during the time the specimens are in storage or being transported.

The Quantisal device collects 1 mL sample of neat oral fluid and dilutes it with 3 mL of preservative buffer in each tube. This results in a 1 to 4 dilution factor.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Quantisal™ Oral Fluid Collection Device

B Predicate 510(k) Number(s):
K200801

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232898	K200801
Device Trade Name	Quantisal™ Oral Fluid Collection Device	Same
General Device Characteristic Similarities		
Intended Use/Indications for Use	For the collection, preservation, and transport of oral fluid specimens for drugs of abuse testing.	Same
Materials	Cellulose pad, polypropylene stem, preservative buffer and transport tube	Same
Body Contact	Cellulose pad placed under the tongue for up to 10 minutes	Same
Sample Collection	A cellulose pad is placed 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
Collector	Collector containing one pad	Same
Sample Volume	1 mL	Same
General Device Characteristic Differences		
Refrigerated Sample Stability	Benzoylecgonine, Morphine, Codeine, Oxycodone, Hydrocodone, 6-Acetylmorphine,	Benzoylecgonine, Morphine, Codeine, Oxycodone, Hydrocodone, 6-Acetylmorphine, Phencyclidine,

	Phencyclidine, Amphetamine, Methamphetamine, Buprenorphine, Methadone, Benzodiazepines, and Tramadol are stable for 12 months when stored refrigerated (2-8ºC, 36-46ºF). THC is stable for 2 months and Cocaine for 1 month when stored refrigerated (2-8ºC, 36-46ºF).	Amphetamine, Methamphetamine, Buprenorphine, Methadone, Benzodiazepines, and Tramadol are stable for 3 months when stored refrigerated (2-8ºC, 36-46ºF) The stability of THC and Cocaine are the same.

VI Standards/Guidance Documents Referenced:

None.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not applicable.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Sample Volume

Data submitted in k200801 to support that a consistent sample volume is collected supports the sample volume claims for the candidate device.

Sample Collection Time

Data submitted in k200801 to support a consistent sample collection time supports the sample collection time claims for the candidate device.

Drug Recovery

The sponsor previously provided in k200801 drug recovery data for THC, benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, nordiazepam, and tramadol which support the drug recovery claims for the candidate device. Use of this device with a drugs of abuse assay intended to measure any other analytes must be validated prior to such use.

Oral Fluid Sample Stability

The sponsor evaluated the stability of the previously cleared analytes and extended their stability claims as follows:

Based upon these results, the sponsor has the following stability:

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
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

Use of this device with a drug of abuse assay intended to measure any other analytes must be validated by the assay manufacturer prior to such use.

Clinical Specimens Testing

The sponsor previously provided in k200801 information on the device performance versus expectoration for THC, benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, benzodiazepines, and tramadol which also supports the performance versus expectoration claims for the candidate device.

Use of this device with a drugs of abuse assay intended to measure any other analytes must be validated by the assay manufacturer prior to such use.

Biocompatibility

The duration of body contact, materials of construction, design, physico-chemical properties and the manufacturing method of Quantisal™ Oral Fluid Collection Device is identical to the predicate device k200801.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.