510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K223781

B Applicant

Immunalysis Corporation

C Proprietary and Established Names

Quantisal™ II 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:

Collection, preservation, and transport of oral fluid specimens for 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™ 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The Quantisal II Oral Fluid Collection Devices has been previously cleared for the measurement of THC, Benzoylecgonine, 6-acetylmorphine, Phencyclidine, Amphetamine, Methamphetamine, Buprenorphine, Methadone, Nordiazepam, 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™ II Oral Fluid Collection Device is intended for the collection, preservation, and transport of oral fluid specimens for drugs of abuse testing. The Quantisal II device simultaneously collects two 1 mL ± 10% oral fluid samples. Each device contains a split collector made up of two cellulose pads affixed to a two component polypropylene stem and two transportation tubes (labelled A and B).

B Principle of Operation:

The Quantisal II device is designed to simultaneously collect two oral fluid samples. Each device contains a split collector made up of two cellulose pads with cellulose extending into the interior of a two-component polypropylene stem. Blue dye is pre-applied to the cellulose inside the stem. When the cellulose pads are 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 windows on the stem. Specimen collection is complete when the windows are completely blue on both sides of the stem. The device stem is split into two separate components, collector 1 and collector 2, each of which contains one half of the stem and a single pad saturated with of oral fluid. The separated pads are transferred into provided polypropylene transport tubes (Tube A and Tube B) which contain 3 mL of preservative buffer each. 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.

V Substantial Equivalence Information:

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

B Predicate 510(k) Number(s):
K183048

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223781	K183048
Device Trade Name	Quantisal II 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
Sample Matrix	Human oral fluid	Same
Sample Volume	1 mL on each pad, 2 mL in total	Same
Materials	Cellulose pad, polypropylene stem, preservative buffer, and transport tube	Same
Contact with human tissue	Cellulose pad placed under the tongue for up to 10 ins	Same
Transport Tube	Polypropylene tube containing preservative buffer	Same
General Device Characteristic Differences		
Refrigerated Sample stability	Benzoylecgonine, Morphine, Codeine, Oxycodone, Hydrocodone, 6-acetylmorphine, Phencyclidine, Amphetamine, Methamphetamine, Buprenorphine, Methadone, Nordiazepam, and Tramadol are stable for 12 months when stored refrigerated (2-8°C; 36-46°F).	THC, Benzoylecgonine, Morphine, Codeine, Oxycodone, Hydrocodone, 6-acetylmorphine, Phencyclidine, Amphetamine, Methamphetamine, Buprenorphine, Methadone, Nordiazepam ,

Device & Predicate Device(s):	K223781	K183048
	THC is stable for 2 months when stored refrigerated (2-8°C; 36-46°F)	and Tramadol are stable for up to one month when stored refrigerated (2-8°C; 36-46°F)

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 k183048 to support that a consistent sample volume is collected supports the sample volume claims for the candidate device.

   Sample Collection Time

   Data submitted in k183048 to support a consistent sample collection time supports the sample collection time claims for the candidate device.

   Drug Recovery

   The sponsor previously provided in k183048 drug recovery data for THC, benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, nordiazepam, and tramadol

which supports 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 has extended their stability claims as follows:

Analyte	Pad A Specimen Stability		Pad B Specimen Stability	
	8-25°C	2-8°C	8-25°C	2-8°C
THC	10 days	2 months	10 days	2 months
Benzoylecgonine	10 days	12 months	10 days	12 months
Cocaine	5 days	1 month	5 days	1 month
Morphine	10 days	12 months	10 days	12 months
Codeine	10 days	12 months	10 days	12 months
Oxycodone	10 days	12 months	10 days	12 months
Hydrocodone	10 days	12 months	10 days	12 months
6-acetylmorphine	10 days	12 months	10 days	12 months
Phencyclidine	10 days	12 months	10 days	12 months
Amphetamine	10 days	12 months	10 days	12 months
Methamphetamine	10 days	12 months	10 days	12 months
Buprenorphine	10 days	12 months	10 days	12 months
Methadone	10 days	12 months	10 days	12 months
Nordiazepam	10 days	12 months	10 days	12 months
Tramadol	10 days	12 months	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 k183048 information on the device performance versus expectoration for THC, benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, nordiazepam, and tramadol which also supports the performance versus expectoration claims for the candidate device.

The sponsor previously provided in k183048 Pad A versus pad B data for THC, benzoylecgonine, cocaine, morphine, codeine, oxycodone, hydrocodone, 6-acetylmorphine, phencyclidine, amphetamine, methamphetamine, buprenorphine, methadone, nordiazepam, and tramadol which also supports the Pad A versus Pad B 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™ II Oral Fluid Collection Device is identical to the predicate device k183048.

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.