December 22, 2021

Immunalysis Corporation
Elina Arroyo
Manager Regulatory Affairs
829 Towne Center Drive
Pomona, California 91767

Re: K203564
Trade/Device Name: SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: October 7, 2021
Received: October 8, 2021

Dear Elina Arroyo:

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, Ph.D.
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 Radiologial Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k203564

Device Name
SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay

Indications for Use *(Describe)*
For In Vitro Diagnostic Use.

The Immunalysis SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 30 ng/mL in neat oral fluid collected by Quantisal or Quantisal II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of oxycodone in human oral fluid with clinical analyzers. This assay is calibrated against oxycodone.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are used.

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

510(k) Number: k203564

A. GENERAL INFORMATION

Applicant Name: Immunalysis Corporation
829 Towne Center Drive
Pomona, CA 91767
Establishment # 2020952

Company Contact: Elina Arroyo, Manager Regulatory Affairs
Immunalysis Corporation
829 Towne Center Drive, Pomona, CA 91767 USA
(224) 361-7080
elina.arroyo@abbott.com

Date Prepared: October 7, 2021

B. DEVICE IDENTIFICATION

Trade or Proprietary Names: SEFRIA™ Oxycodone Oral Fluid Enzyme Immunoassay

Common Name: Oxycodone Oral Fluid Enzyme Immunoassay

C. REGULATORY INFORMATION

Device Classification Name: Enzyme Immunoassay, Opiates

Product Codes: DJG

Regulatory Class: Class II

Classification Regulation: 862.3650

Panel: Toxicology (91)

Predicate Device: Thermo Scientific CEDIA Opiate OFT Assay [K101754]

D. DEVICE DESCRIPTION

The SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay is an *in vitro* test to detect the presence of oxycodone in human oral fluid samples collected by Quantisal or Quantisal II Oral Fluid Collection Device.

Oxycodone was developed in Germany in 1916, intended to be a better medication than other opioids such as codeine and morphine but unfortunately has significant potential for abuse and addiction. It is an opioid analgesic, most often prescribed to control moderate to severe pain; one in 16 surgical patients becomes a long-term user. Overprescribing opioids after surgery is common, and the lack of multidisciplinary procedure-specific guidelines contributes to the wide variation in opioid prescribing practice.[1] Oxycodone is present in formulations combined with other pain-relieving drugs like acetaminophen (Percocet®) or as extended release tablets (OxyContin®). The disposition of oxycodone in oral fluid has been well documented showing the main drug found after intake is the parent compound. After a single dose of 20 mg oxycodone, concentrations as high as 200 ng/mL may be detected in oral fluid.[2] Oral fluid has been shown to be a useful matrix for the analysis of oxycodone in patients undergoing addiction treatment.[3], [4]

E. INTENDED USE

For *In Vitro* Diagnostic Use.

The Immunalysis SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay is a homogeneous enzyme immunoassay with a cutoff of 30 ng/mL in neat oral fluid collected by Quantisal or Quantisal II Oral Fluid Collection Device. The assay is intended for the qualitative and semi-quantitative analysis of oxycodone in human oral fluid with clinical analyzers. This assay is calibrated against oxycodone.

The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The Immunalysis SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/ Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are used.

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[1] Overton HN, Hanna MN, Bruhn WE, Hutfless S, Bicket MC, Makary MA. Opioid-prescribing guidelines for common surgical procedures: An Expert Panel Consensus. J Am Coll Surg. 2018 Oct;227(4):411-418.

[2] Cone EJ, DePriest AZ, Heltsley R, Black DL, Mitchell JM, LoDico C, Flegel R. Prescription Opioids. III. Disposition of oxycodone in oral fluid and blood following controlled single-dose administration. J Anal Toxicol. 2015;39(3):192-202.

[3] Kunkel F, Fey E, Borg D, Stripp R, Getto C. Assessment of the use of oral fluid as a matrix for drug monitoring in patients undergoing treatment for opioid addiction. J Opioid Manag. 2015;11(5):435-42.

[4] Conermann T, Gosalia AR, Kabazie AJ, Moore C, Miller K, Fetsch M, Irvan D. Utility of oral fluid in compliance monitoring of opioid medications. Pain Physician. 2014;17(1):63-70.

F. COMPARISON WITH PREDICATE

The selected predicate device is Thermo Scientific CEDIA Opiate OFT Assay K101754.

Attribute	Candidate Device SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay	Predicate Device Thermo Scientific CEDIA Opiate OFT Assay [K101754]
Similarities		
Test Principle	Identical	Homogeneous enzyme immunoassay
Assay Materials	Identical	antibody reagent, drug conjugate reagent
Cutoff Level	Identical	30 ng/mL in Neat Oral Fluid
User Environment	Identical	For use in laboratories
Sample Matrix	Identical	Human oral fluid
Reagent Storage	Identical	2-8°C until expiration date
Instrumentation	Identical	Automated clinical chemistry analyzer
Mass Spectrometry Confirmation	Identical	Required for preliminary positive analytical results
Differences		
Intended Use	Qualitative and semi-quantitative analysis of oxycodone in human oral fluid collected by Quantisal or Quantisal II Oral Fluid Collection Device	Qualitative determination of opiates in human oral fluid collected by Oral-Eze™ Saliva Collection System
Calibrated Against	Oxycodone	Morphine
Sample Collection Device	Oral fluid is collected with the Quantisal and Quantisal II Oral Fluid Collection Device. Sample is stored in a plastic tube containing preservative buffer with snap cap.	Oral fluid is collected with the Oral-Eze™ Saliva Collection System. Sample is stored in a plastic tube containing preservative buffer with snap cap.

G. PERFORMANCE CHARACTERISTICS

The following laboratory performance studies were performed to determine substantial equivalence of the SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay to the predicate device. Assay performance was established using the Beckman Coulter AU480 chemistry analyzer.

1. Precision

Precision study was performed over 15 days, 2 runs per day with 2 collection devices per run (N=60),

one replicate per collection device on 1 lot of reagent and 1 lot of Quantisal and 1 lot of Quantisal II oral fluid collection devices. Drug free negative oral fluid was spiked to concentrations of assay cutoff and ±25%, ±50%, ±75%, ±100% of the cutoff and was collected using the collection devices. The spiked concentrations were confirmed by mass spectrometry (LC-MS/MS) before collection. The study established the repeatability of the testing system, including assay and oral fluid collection device. Test results in qualitative and semi-quantitative modes are presented in **Tables 1** to **6**.

An additional 20-day study was performed on 3 lots of assay reagent to demonstrate the repeatability across multiple reagent lots.

Table 1. Precision – Qualitative - Quantisal

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	31 Neg/29 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Table 2. Precision - Semi-Quantitative - Quantisal

Concentration (ng/mL)	% of Cutoff	# of Determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	-0.2	60 Negative
7.5	-75%	60	8.4	60 Negative
15	-50%	60	16.7	60 Negative
22.5	-25%	60	24.3	60 Negative
30	Cutoff	60	32.3	16 Neg/44 Pos
37.5	+25%	60	42.1	60 Positive
45	+50%	60	53.3	60 Positive
52.5	+75%	60	64.3	60 Positive
60	+100%	60	76.3	60 Positive

Table 3. Precision – Qualitative – Quantisal II Pad A

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
22.5	-25%	60	60 Negative
30	Cutoff	60	31 Neg/29 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Table 4. Precision - Semi-Quantitative – Quantisal II Pad A

Concentration (ng/mL)	% of Cutoff	# of Determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	0.5	60 Negative
7.5	-75%	60	7.3	60 Negative
15	-50%	60	14.7	60 Negative
22.5	-25%	60	21.7	60 Negative
30	Cutoff	60	29.9	36 Neg/24 Pos
37.5	+25%	60	42.4	60 Positive
45	+50%	60	50.9	60 Positive
52.5	+75%	60	57.3	60 Positive
60	+100%	60	66.5	60 Positive

Table 5. Precision – Qualitative – Quantisal II Pad B

Concentration (ng/mL)	% of Cutoff	# of Determinations	Result
0	-100%	60	60 Negative
7.5	-75%	60	60 Negative
15	-50%	60	60 Negative
22.5	-25%	60	60 Negative
30	Cutoff	60	28 Neg/32 Pos
37.5	+25%	60	60 Positive
45	+50%	60	60 Positive
52.5	+75%	60	60 Positive
60	+100%	60	60 Positive

Table 6. Precision - Semi-Quantitative - Quantisal II Pad B

Concentration (ng/mL)	% of Cutoff	# of Determinations	Mean Conc. (ng/mL)	Result
0	-100%	60	0.3	60 Negative
7.5	-75%	60	7.0	60 Negative

Concentration (ng/mL)	% of Cutoff	# of Determinations	Mean Conc. (ng/mL)	Result
15	-50%	60	14.9	60 Negative
22.5	-25%	60	22.7	60 Negative
30	Cutoff	60	30.8	28 Neg/32 Pos
37.5	+25%	60	42.9	60 Positive
45	+50%	60	49.4	60 Positive
52.5	+75%	60	58.3	60 Positive
60	+100%	60	67.1	60 Positive

2. Specificity and Cross-Reactivity

Structurally and functionally similar compounds were spiked into drug free pooled oral fluid at levels that will yield a result that is equivalent to the cutoff, if cross reacting. The study verified the cross reactivity of the oxycodone assay to related drugs and drug metabolites, in both the qualitative and semi-quantitative modes. Cross-reactivity test results in qualitative mode are presented in **Table 7**. Cross-reactivity test results in semi-quantitative mode are presented in **Table 8**.

Table 7. Cross-Reactivity – Qualitative

Compound	Compound Conc. (ng/mL)	Oxycodone Equivalent Conc. (ng/mL)	Result	Cross-Reactivity (%)
6-acetylcodeine	40,000	<30	NEG	<0.08
6-acetylmorphine	40,000	<30	NEG	<0.08
Buprenorphine	40,000	<30	NEG	<0.08
Codeine	40,000	<30	NEG	<0.08
Desomorphine	40,000	<30	NEG	<0.08
Dihydrocodeine	40,000	<30	NEG	<0.08
Ethylmorphine	40,000	<30	NEG	<0.08
Fentanyl	40,000	<30	NEG	<0.08
Heroin	40,000	<30	NEG	<0.08
Hydrocodone	40,000	<30	NEG	<0.08
Hydromorphone	40,000	<30	NEG	<0.08
Levorphanol	40,000	<30	NEG	<0.08
Meperidine	40,000	<30	NEG	<0.08
Morphine	40,000	<30	NEG	<0.08
Morphine-3-β-D-glucuronide	40,000	<30	NEG	<0.08
Morphine-6-β-D-glucuronide	40,000	<30	NEG	<0.08
Naloxone	6,000	30	POS	0.5
Naltrexone	40,000	<30	NEG	<0.08
Norbuprenorphine	40,000	<30	NEG	<0.08
Norcodeine	40,000	<30	NEG	<0.08
Normorphine	40,000	<30	NEG	<0.08
Noroxycodone	4,750	30	POS	0.6
Noroxymorphone	12,500	30	POS	0.2

Compound	Compound Conc. (ng/mL)	Oxycodone Equivalent Conc. (ng/mL)	Result	Cross-Reactivity (%)
Oxymorphone	35	30	POS	85.7
Oxymorphone-3-β-D-glucuronide	550	30	POS	5.5
Tapentadol	40,000	<30	NEG	<0.08
Tramadol	40,000	<30	NEG	<0.08

Table 8. Cross-Reactivity – Semi-Quantitative

Compound	Compound Conc. (ng/mL)	Oxycodone Equivalent Conc. (ng/mL)	Mean Value (ng/mL)	Result	Cross-Reactivity (%)
6-acetylcodeine	40,000	<30	3.1	NEG	<0.08
6-acetylmorphine	40,000	<30	2.1	NEG	<0.08
Buprenorphine	40,000	<30	1.4	NEG	<0.08
Codeine	40,000	<30	3.1	NEG	<0.08
Desomorphine	40,000	<30	3.2	NEG	<0.08
Dihydrocodeine	40,000	<30	4.0	NEG	<0.08
Ethylmorphine	40,000	<30	4.9	NEG	<0.08
Fentanyl	40,000	<30	2.1	NEG	<0.08
Heroin	40,000	<30	1.9	NEG	<0.08
Hydrocodone	40,000	<30	4.7	NEG	<0.08
Hydromorphone	40,000	<30	4.1	NEG	<0.08
Levorphanol	40,000	<30	2.9	NEG	<0.08
Meperidine	40,000	<30	1.8	NEG	<0.08
Morphine	40,000	<30	4.0	NEG	<0.08
Morphine-3-β-D-glucuronide	40,000	<30	1.3	NEG	<0.08
Morphine-6-β-D-glucuronide	40,000	<30	1.2	NEG	<0.08
Naloxone	6,000	30	32.5	POS	0.5
Naltrexone	40,000	<30	19.8	NEG	<0.08
Norbuprenorphine	40,000	<30	1.3	NEG	<0.08
Norcodeine	40,000	<30	1.4	NEG	<0.08
Normorphine	40,000	<30	1.4	NEG	<0.08
Noroxycodone	4,750	30	32.6	POS	0.6
Noroxymorphone	12,500	30	33.0	POS	0.2
Oxymorphone	35	30	31.0	POS	85.7
Oxymorphone-3-β-D-glucuronide	550	30	30.3	POS	5.5
Tapentadol	40,000	<30	1.6	NEG	<0.08
Tramadol	40,000	<30	1.8	NEG	<0.08

3. Interference – Structurally Unrelated Compounds

Structurally unrelated compounds were evaluated in qualitative and semi-quantitative modes by spiking the potential interferent into drug free oral fluid containing oxycodone at ±25% of the cutoff. At the levels tested, there was no interference with structurally unrelated compounds. The concentration levels of structurally unrelated compounds are presented in **Table 9**.

Table 9. Non-Interfering Structurally Unrelated Compounds

Compound	Conc. Tested (ng/mL)
4-Bromo-2,5,Dimethoxyphenethylamine	40,000
Alprazolam	40,000
7-Aminoclonazepam	40,000
7-Aminoflunitrazepam	40,000
7-Aminonitrazepam	40,000
Amitriptyline	40,000
S-(+) Amphetamine	40,000
Benzylpiperazine	40,000
Bromazepam	40,000
Bupropion	40,000
Butabarbital	40,000
Butalbital	40,000
Cannabidiol	40,000
Cannabinol	40,000
Carbamazepine	40,000
Carisoprodol	40,000
Chlordiazepoxide	40,000
Chlorpromazine	20,000
Clobazam	40,000
Clomipramine	40,000
Clonazepam	40,000
Clozapine	40,000
Cocaine	40,000
Cotinine	40,000
Cyclobenzaprine	40,000
Demoxepam	40,000
Desalkylflurazepam	40,000
Desipramine	40,000
Diazepam	40,000
Digoxin	40,000
Dehydronorketamine	40,000
Delta-9-THC	40,000
Diphenhydramine	40,000
Dextromethorphan	40,000
Doxepin	40,000
Ecgonine	40,000
Ecgonine Methyl Ester	40,000

Compound	Conc. Tested (ng/mL)
EDDP	40,000
EMDP	40,000
1R,2S(-)-Ephedrine	40,000
1S,2R(+)-Ephedrine	40,000
Ethyl-β-D-Glucuronide	40,000
Fenfluramine	40,000
Flunitrazepam	40,000
Fluoxetine	40,000
Flurazepam	40,000
Haloperidol	40,000
11-hydroxy-delta-9-THC	40,000
Imipramine	40,000
Ketamine	40,000
Lamotrigine	40,000
Lidocaine	40,000
Lorazepam	40,000
Lorazepam Glucuronide	40,000
Lormetazepam	40,000
LSD	40,000
Maprotiline	40,000
MDA	40,000
MDEA	40,000
MDMA	40,000
Meprobamate	40,000
S(+)-Methamphetamine	40,000
Methadone	40,000
Methaqualone	40,000
Methoxetamine	40,000
Methylone	40,000
Methylphenidate	40,000
Midazolam	40,000
N-desmethyltapentadol	40,000
N-desmethyl tramadol	40,000
N-desmethyl venlafaxine	40,000
Nalorphine	40,000
Nitrazepam	40,000
11-nor-9 carboxy THC	40,000
Nordiazepam	40,000
Norketamine	40,000

Compound	Conc. Tested (ng/mL)
Norpropoxyphene	40,000
Norpseudoephedrine	40,000
Nortriptyline	40,000
O-desmethyl tramadol	40,000
O-desmethyl venlafaxine	40,000
Olanzapine	40,000
Oxazepam	40,000
Pentazocine	40,000
Pentobarbital	40,000
Phencyclidine	40,000
Phenobarbital	40,000
Phentermine	40,000
Phenylephrine	40,000
Phenytoin	40,000
Phenylpropanolamine	40,000
PMA	40,000
Prazepam	40,000
Propranolol	40,000
Propoxyphene	40,000
Protriptyline	40,000
R,R(-)-Pseudoephedrine	40,000
S,S(+)-Pseudoephedrine	40,000
Ritalinic Acid	40,000
Salicylic Acid	40,000
Secobarbital	40,000
Sertraline	40,000
Sufentanil	40,000
Temazepam	40,000
Theophylline	40,000
Thioridazine	40,000
Trazadone	40,000
Triazolam	40,000
Trifluoromethylphenyl-piperazine	40,000
Trimipramine	40,000
Venlafaxine	40,000
Verapamil	40,000
Zolpidem Tartrate	40,000

4. Interference – Endogenous Compounds and Exogenous Compounds

Endogenous compounds and exogenous compounds were evaluated in qualitative and semi-quantitative modes by spiking the potential interferent into drug free oral fluid containing oxycodone at ±25% of the cutoff. Additional orally used products were tested by collecting oral fluid using Quantisal and Quantisal II Oral Fluid Collection Devices from volunteers after use of the substances. At the levels tested, there was no interference observed with endogenous compounds, exogenous compounds and orally used compounds. Endogenous compounds and exogenous compounds are presented in **Tables 10 and 11**. Orally used compounds are presented in **Table 12**.

Table 10. Non-interfering Endogenous Compounds

Compound	Concentration Tested
Ascorbic Acid	3 mg/mL
Bilirubin	0.15 mg/mL
Cholesterol	0.45 mg/mL
γ-Globulin	0.8 mg/mL
Hemoglobin	3 mg/mL
Human Serum Albumin	15 mg/mL
IgA	1 mg/mL
IgG	1 mg/mL
IgM	0.5 mg/mL
Salivary-α-amylase	1000 U/mL

Table 11. Non-interfering Exogenous Compounds

Compound	Concentration Tested
Acetaminophen	0.1 mg/mL
Acetylsalicylic Acid	0.1 mg/mL
Baking Soda	0.6% v/v
Denture Adhesive	0.6% w/v
Ibuprofen	0.1 mg/mL
Alcohol (Ethanol)	6% v/v
Caffeine	0.1 mg/mL
Cough Syrup	6% v/v
Coffee	6% v/v
Cranberry Juice	6% v/v
Hydrogen Peroxide (3% OTC)	0.5% v/v
Milk	1% v/v
Mouthwash	6% v/v
Naproxen	0.1 mg/mL
Orange Juice	6% v/v
Soft Drink (Pepsi)	6% v/v
Sodium Chloride	18 mg/mL
Sugar	50 mg/mL
Tea	6% v/v
Toothpaste	6% v/v

Table 12. Non-interfering Orally Used Exogenous Products

Compound	Concentration Tested
Teeth Whitener	2 strips
Cigarette	1 cigarette
Hard Candy	1 piece
Chewing Gum	1 piece
Hydrogen Peroxide (3% OTC)	Neat (2 min. mouth rinse)
Sugar	2 Teaspoons
Cough Syrup	2 Teaspoons

5. Interference – pH

To evaluate potential interference from the effect of oral fluid pH, device performance in the qualitative and semi-quantitative modes was tested using a range of oral fluid pH values (3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 and 11.0). All test samples were prepared in drug free oral fluid containing oxycodone at ±25% of the cutoff. At the pH levels tested, there was no interference observed for each test mode.

6. Linearity/Recovery

Assay linearity was evaluated in the semi-quantitative mode by spiking a drug free oral fluid pool with a high concentration of oxycodone. Additional pools were made by serially diluting the high concentration specimen with drug free oral fluid to achieve concentrations ranging from 10 ng/mL to 110 ng/mL. The 0 ng/mL specimen was made from drug free oral fluid. Each pool was collected by Quantisal and Quantisal II oral fluid collection devices and tested in triplicate to calculate the mean concentration values that were used to calculate drug recovery. Linearity test results in semi-quantitative mode are presented in **Tables 13** to **15**. The study confirmed the linear range to be 10-100 ng/mL with a drug recovery percentage of 90.6% to 111.6% across the collection devices.

Table 13. Linearity/Recovery – Quantisal

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	1.8	N/A
10	9.6	95.7
20	21.0	104.8
30	33.2	110.6
40	40.7	101.8
50	55.8	111.6
60	60.5	100.8
70	75.8	108.2
80	80.9	101.2
90	95.6	106.2
100	106.7	106.7
110	112.4	102.2

Table 14. Linearity/Recovery – Quantisal II "A"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	-1.5	N/A
10	10.2	102.0
20	20.4	102.2
30	29.8	99.2
40	42.0	104.9
50	50.2	100.3
60	57.1	95.2
70	69.4	99.1
80	81.9	102.3
90	87.9	97.7
100	107.7	107.7
110	109.7	99.7

Table 15. Linearity/Recovery – Quantisal II "B"

Expected Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
0	-1.2	N/A
10	10.9	108.7
20	19.4	97.0
30	27.2	90.6
40	43.0	107.5
50	46.7	93.5
60	59.9	99.8
70	74.3	106.2
80	85.4	106.8
90	90.8	100.9
100	105.4	105.4
110	117.7	107.0

7. Oxycodone Stability in Oral Fluid

Drug free negative oral fluid spiked with oxycodone at +50% of the 30 ng/mL cutoff were collected and stored in Quantisal and Quantisal II Oral Fluid Collection Devices at 2°C - 8°C, tested by LC-MS/MS at each time point and compared to the baseline concentration result. The test results indicate that oral fluid samples containing oxycodone are stable for up to 12 months stored in Quantisal or Quantisal II Oral Fluid Collection Device at 2°C - 8°C.

Data to support 10-day storage in Quantisal or Quantisal II Oral Fluid Collection Device at ambient temperature 8°C - 25°C were reported in K183048 and K200801.

8. Calibration Duration

Drug free negative oral fluid spiked with oxycodone at ±25% of the cutoff were tested in qualitative

mode at time points up to 14 days and in semi-quantitative at time points up to 25 days. At the initial time point, a two-point calibration curve was established in qualitative mode and multi-points calibration curve was established in semi-quantitative mode. These calibrations were used through the duration of the study. The test results met acceptance criteria at each time point up to 24 days. The recommended frequency of calibration is 14 days.

9. Method Comparison

Eighty (80) deidentified, unaltered clinical oral fluid samples collected by Quantisal and Quantisal II Oral Fluid Collection Devices were obtained from clinical research facilities, analyzed for oxycodone at assay cutoff with the SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay in both qualitative and semi-quantitative modes and compared to Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) results. The instruments used were the Beckman Coulter AU480 chemistry analyzer and an Agilent 6430 Liquid Chromatography-Tandem Mass Spectrometry. The data demonstrate that the design goal of greater than 95% agreement was achieved. Method comparison test results in qualitative and semi-quantitative modes are presented from **Tables 16** to **18**.

Table 16. Method Comparison – Quantisal

Immunoassay Result		**LC-MS/MS Oxycodone Concentration**				**Agreement (%)**
		< 15 ng/mL (less than -50% cutoff)	**15 – 29 ng/mL (between -50% cutoff and cutoff)**	**30 – 45 ng/mL (between cutoff and +50% cutoff)**	**> 45 ng/mL (greater than +50% cutoff)**	
Qual.	Positive	0	0	5	35	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**
Semi-Quant.	Positive	0	0	5	35	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**

Table 17. Method Comparison – Quantisal II "A"

Immunoassay Result		**LC-MS/MS Oxycodone Concentration**				**Agreement (%)**
		< 15 ng/mL (less than -50% cutoff)	**15 – 29 ng/mL (between -50% cutoff and cutoff)**	**30 – 45 ng/mL (between cutoff and +50% cutoff)**	**> 45 ng/mL (greater than +50% cutoff)**	
Qual.	Positive	0	0	5	35	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**
Semi-Quant.	Positive	0	0	5	35	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**

Table 18. Method Comparison – Quantisal II "B"

Immunoassay Result		LC-MS/MS Oxycodone Concentration				Agreement (%)
		< 15 ng/mL (less than -50% cutoff)	**15 – 29 ng/mL (between -50% cutoff and cutoff)**	**30 – 45 ng/mL (between cutoff and +50% cutoff)**	**> 45 ng/mL (greater than +50% cutoff)**	
Qual.	Positive	0	0	5	35	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**
Semi-Quant.	Positive	0	0	5	35	**100% (40/40)**
	Negative	36	4	0	0	**100% (40/40)**

H. CONCLUSION

The information provided in this pre-market notification demonstrates that the SEFRIA Oxycodone Oral Fluid Enzyme Immunoassay is substantially equivalent to the legally marketed predicate device for its intended use.