K030234

PREMARKET NOTIFICATION [510(k)] SUMMARY

APR 2 8 2003

Submitter	Cozart Bioscience Ltd 45 Milton Park Abingdon Oxfordshire OX14 4RU UK Tel No: 01235 861483 Fax No: 01235 835607
Contact Person	Dr Roberto Liddi Quality Assurance & Regulatory Affairs Manager
Date	20th January 2003
Device Name	Cozart EIA Cocaine Oral Fluid Kit
Trade Name	Cozart EIA Cocaine Oral Fluid Kit
Classification Name	Cocaine Test System

Classification

Class II
Code of Federal Regulations Title 21 Food and Drugs
Part 862 Clinical Chemistry and Clinical Toxicology Devices
Subpart D Clinical Toxicology Test Systems
862.3250 Cocaine and cocaine metabolite test system

Establishment Registration No

3002336046

Performance Standards

BS EN ISO 9001:1994; EN 46001:1996

Substantial Equivalence

STC Opiates Micro-Plate EIA (Orasure® Application), 510(k) no. K981341

Parameter	Cozart EIA Cocaine Oral Fluid Kit	Cocaine Metabolite Micro-Plate EIA (Orasure® Application), 510(k) no. K982061
Intended Use	Qualitative test for Cocaine in human oral fluid with a 30ng/ml cutoff. Recommend confirmation of positive results by GC/MS.	Qualitative test for Cocaine in human oral fluid with a 10ng/ml cutoff. Recommend confirmation of positive results by GC/MS.
Target Population	Clinical and forensic samples.	Clinical samples.
Design	Competitive ELISA	Competitive ELISA
Enzyme	Horse Radish Peroxidase	Horse Radish Peroxidase
Results	Read spectrophotometrically at 450nm.	Read spectrophotometrically at 450nm.
Calibrators	0, 5, 10, 50ng/mL	0, 5, 10, 50ng/mL
Matrix	Human Oral Fluid	Human Oral Fluid
Controls	None supplied but Cozart recommends using external controls.	Unknown
Method Comparison	177 samples were tested, 100 screened positive for cocaine and metabolites, of which 100 were confirmed positive by GC/MS. 77 samples screened negative for cocaine and metabolites and 71 were confirmed negative by GC/MS.	92% Agreement as compared to GC/MS
Precision	CV (%) of 1.9 – 10.7%	CV (%) of 5 – 11.2%
Sensitivity	1.8ng/mL	<5ng/mL
Specificity	29 potential interferents tested – none cross-reacted.	Unknown

Introduction

The Cozart EIA Cocaine Oral Fluid Kit is a laboratory based test for the detection of cocaine and metabolites in human oral fluid using a cutoff equivalent to 30ng/mL. The device detailed above was compared to Gas Chromatography/Mass Spectrometry (GC/MS).
Cozart Bioscience Ltd is the manufacturer of the Opiates Oral Fluid Kit. We have not purchased this device from another manufacturer and the device is not marketed under another product name.

Intended Use

The Cozart EIA Cocaine Oral Fluid Kit is intended for use in clinical and forensic laboratories when used in conjunction with the Cozart RapiScan Oral Fluid collection system. Using this collection system it provides qualitative screening results for cocaine and metabolites in human oral fluid at a cutoff concentration of 10ng/ml. This is equal to 30ng/mL in undiluted oral fluid as the collection system involves a 1:3 dilution of the sample.
The remainder of this document will refer to the 10ng/mL cutoff concentration.

This assay is for professional use only and provides only a preliminary analytical test result. Clinical consideration and professional judgement must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive

result. In order to obtain a more confirmed analytical result a more specific alternative chemical method is needed. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

Target Population

The target population for the Cozart EIA Cocaine Oral Fluid Kit is clinical and forensic samples.

Where Used

The Cozart EIA Cocaine Oral Fluid Kit is designed for use in clinical and forensic laboratories. For professional use only.

Design

As can be seen from the Principle of the Test section in the pack insert, the Cozart EIA Cocaine Oral Fluid Kit is a competitive ELISA for the detection of cocaine and its metabolites in human oral fluid.

Materials

The Cozart EIA Cocaine Oral Fluid kit supplies the following reagents – a microtitre plate coated with antibody, enzyme conjugate reagent, wash buffer, substrate solution, stop solution and four calibrators (0, 5, 10 and 50ng/ml benzoylecgonine in oral fluid matrix).

Performance

Method Comparison

The Cozart EIA Cocaine Oral Fluid Kit was compared to Gas Chromatography/Mass Spectrometry (GC/MS). All the samples were tested with the Cozart EIA Cocaine Oral Fluid Kit according to the pack insert enclosed.
177 samples were tested through the Cozart EIA Cocaine Oral Fluid Kit, 100 screened positive and 100 were confirmed positive by GC/MS. 77 samples screened negative and 71 were confirmed negative by GC/MS. Of the 177 samples tested 15 were between – 50% cutoff and +50% cutoff.

New Device		GC/MS Negs	Near Cutoff GC/MS Negs *	Near Cutoff GC/MS Pos **	GC/MS Pos***	Percent Agreement with GC/MS
Pos	100	0	0	4	100	100
Neg	77	71	6	5	6	92

* Between –50% Cutoff and the Cutoff.
** Between +50% Cutoff and the Cutoff.
*** Total number of positives (includes near cutoff samples).

96% overall agreement as compared with GC/MS

Precision

The precision obtained for the Cozart EIA Cocaine Oral Fluid Kit produced CVs less than 9%. The total precision for the kit produced CVs less than 11%. The Cozart EIA Cocaine Oral Fluid Kit is a qualitative manual ELISA assay and CVs of less than 10% are acceptable for this assay type.

Sensitivity

The sensitivity of the Cozart EIA Cocaine Oral Fluid Kit is 1.8ng/ml.

Specificity

Twenty-nine potentially interfering unrelated substances were tested for cross reactivity in the Cozart Cocaine Oral Fluid Kit and none were found to cross react. Four related compounds were tested and three showed a level of cross reactivity.

Cutoff Concentration

Testing samples at the cutoff concentration, 50% above and 50% below were carried out to validate the cutoff concentration. The absorbances obtained for the 5ng/ml sample were all higher than the 10ng/ml cutoff calibrator. Similarly the absorbances obtained for the 15ng/ml sample were all lower than the 10ng/ml cutoff calibrator.

Interference Studies

A range of parameters including alcohol, sample adequacy indicator dye, haemoglobin, smoking, coffee, tea, water, food, orange juice, hard candy, chewing gum and mouthwash were tested for interference in the Cozart Cocaine Oral Fluid Kit. No interference was observed with any of the parameters.

Stopped Assay Stability

The stability of the stopped assay was investigated by reading the absorbance at 450nm at times 0, 5, 10, 15, 30, 45 and 60 minutes. The Cozart EIA Cocaine Oral Fluid Kit must be read within 15 minutes at 450nm.

Assay Drift

Sample addition at time 0, 2.5, 5, 7.5, 10, 12.5, 15, 17.5, 20, 22.5 and 25 minutes was investigated. Little change was observed across the plate and therefore sample addition to a Cozart EIA Cocaine Oral Fluid Kit must take place within 25 minutes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 8 2003

Dr. Roberto Liddi
Quality Assurance & Regulatory Affairs Manager
Cozart Bioscience Ltd
45 Milton Park
Abingdon
Oxfordshire OX14 4RU
UK

Re: k030234
Trade/Device Name: Cozart EIA Cocaine Oral Fluid Kit
Regulation Number: 21 CFR 862.3250
Regulation Name: Specimen transport and storage container
Regulatory Class: Class II
Product Code: DIO
Dated: April 15, 2003
Received: April 18 2003

Dear Dr. Liddi:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030234

Device Name: **Cozart EIA Cocaine Oral Fluid Kit**

Indications For Use:

The Cozart EIA Cocaine Oral Fluid Kit is intended for use in clinical and analytical laboratories when used in conjunction with the Cozart RapiScan Oral Fluid collection system. Using this collection system it provides qualitative screening results for cocaine and metabolites in human oral fluid at a cutoff concentration of 10ng/ml. This is equal to 30ng/mL in undiluted oral fluid as the collection system involves a 1:3 dilution of the sample.

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(Division Sign-Off)
Division of Clinical Labor...
510(k) Number K030234

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rx ✓

(Optional Format 3-10-98)