DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

APR 0 7 2003

Re: k024339
Trade/Device Name: Cozart EIA Opiate Oral Fluid Kit
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DIG
Dated: March 18, 2003
Received: March 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): K024339

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

Indications For Use:

The Cozart EIA Opiates 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 Opiates 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.

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024339

(Optional Format 3-10-98)

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PRESCRIPTION USE