APR 17 2002 K013882

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.92)

807.92 (a):

1. *Submitter's Name:* OraSure Technologies, Inc.
   Address: 150 Webster St., Bethlehem, PA 18015
   Telephone Number: (610) 882-1820
   Contact Person: R. Sam Niedbala, Ph.D., BCFE
   Date Prepared: April 10, 2002

2. *Device Name:*
   Proprietary Name: Benzodiazepines Intercept® MICRO-PLATE EIA
   Usual Name: Benzodiazepines Intercept® System
   Classification Name: Enzyme Immunoassay, Benzodiazepine

3. *Device to Which Substantial Equivalence Is Claimed:*
   Roche Diagnostic Systems, Abuscreen ONLINE® kit for Benzodiazepines (urine); K914509

4. *Description of Device:*
   Principle of the Assay
   The OTI Benzodiazepines Intercept® MICRO-PLATE EIA is a competitive micro-plate immunoassay for the detection of benzodiazepines in oral fluid collected with the Intercept® Oral Fluid Drug Test Oral Specimen Collection Device. Specimen or standard is added to an EIA well in combination with an enzyme-labeled hapten derivative. In an EIA well containing an oral fluid specimen positive for benzodiazepines, there is a competition between the drug and the enzyme-labeled hapten to bind the antibody fixed onto the EIA well. EIA wells are then washed, substrate is added, and color is produced. The absorbance measured for each well at 450 nm is inversely proportional to the amount of benzodiazepines present in the specimen or calibrator/control. Because currently there are no SAMHSA assigned cutoffs for benzodiazepines testing using oral fluid, OTI recommends a cutoff of 1.0 ng/mL when testing oral fluid collected with the Intercept® Oral Fluid Drug Test Oral Specimen Collection Device. This cutoff is within the limit of detection by the OTI Benzodiazepines Intercept® MICRO-PLATE EIA.

5. *Intended Use Statement:*
   The OTI Benzodiazepines Intercept® MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of benzodiazepines in oral fluid collected with the Intercept® Oral Fluid Drug Test Oral Specimen Collection Device using a 1.0 ng/mL(nordiazepine) cutoff. **For *In Vitro* Diagnostic Use.**

   The OTI Benzodiazepines Intercept® MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

6. a. *Summary of Technological Characteristics:*
   The OTI Benzodiazepines Intercept® MICRO-PLATE EIA is based on the principle of solid phase competitive enzyme immunoassay. This application is for the use of the OTI Benzodiazepines EIA as a screening tool for the detection of benzodiazepines using specimens collected with the OTI Intercept® Oral Fluid Drug Test Oral Specimen Collection Device.

b. *Summary of Performance Data:*

The performance characteristics of the OTI Benzodiazepines Intercept® MICRO-PLATE EIA are summarized below. This information concludes that the performance of this device is essentially equivalent to the legally marketed predicate device.

	Proposed: Benzodiazepines Intercept® MICRO-PLATE EIA	**Previously Cleared (K914509):** Abuscreen ONLINE® kit for Benzodiazepines
Performance Characteristics:		
Precision		
Intra-assay %CV range	4.9-6.5%	2-7%
Inter-assay %CV range	7.6-11.4%	2-10%
Limit of Detection	0.2 ng/mL	< 10 ng/mL
% Cross-Reactivity		
α-Hydroxyalprazolam	10%	112%
α-Hydroxytriazolam	15%	98%
Alprazolam	151%	96%
7-Aminoflunitrazepam	6%	Not tested
7-Aminonitrazepam	8%	52%
Bromazepam	2%	75%
Clorazepate	70%	43%
Chlordiazepoxide	6%	55%
Clonazepam	1%	56%
Desalkylflurazepam	17%	49%
Diazepam	135%	105%
Estazolam	130%	Not tested
Flurazepam	49%	61%
2-Hydroxyethylflurazepam	8%	88%
Lorazepam	< 1%	59%
Medazepam	17%	40%
Midazolam	49%	96%
Nitrazepam	39%	81%
Norchlordiazepoxide	3%	Not tested
Oxaprozin	< 1%	Not tested
Oxazepam	7%	98%
Prazepam	107%	84%
Temazepam	55%	Not tested
Triazolam	26%	96%
Clinical Accuracy	Three separate population studies were performed to characterize performance of the Intercept Test. A total of 149 specimens were collected from all three populations. The table below summarizes the performance of the Intercept kit with all specimens tested by immunoassay and GC/MS/MS.	N=50 confirmed positive. 42 positive, 8 negative

Intercept Result	No Drug Detected by GC/MS/MS	0.18-0.49	0.5-0.99ng/mL	1.0-1.5ng/mL	>1.5
Positive	4	5	1	2	26
Negative	93	7	3	4	4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

R. Sam Niedbala, Ph.D., BCFE
Chief Science Officer
OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015

APR 17 2002

Re: k013882
Trade/Device Name: OTI BENZODIAZEPINES INTERCEPT® MICRO-PLATE EIA
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: Class II
Product Code: JXM
Dated: March 12, 2002
Received: March 14, 2002

Dear Dr. Niedbala:

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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: OTI BENZODIAZEPINES INTERCEPT® MICRO-PLATE EIA

Indications For Use:

The OTI Benzodiazepines Intercept® MICRO-PLATE EIA is intended for use by clinical laboratories in the qualitative determination of benzodiazepines in oral fluid collected with the Intercept® Oral Fluid Drug Test Oral Specimen Collection Device using a 1.0 ng/mL cutoff. FOR *IN VITRO* DIAGNOSTIC USE.

The OTI Benzodiazepines Intercept® MICRO-PLATE EIA provides only a preliminary analytical test result. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when a preliminary, positive result is observed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Von Dz Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013882

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

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