NOV 0 5 2001

K012396

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Jennifer Tribbett

Date Prepared: October 2, 2001

2) Device Name

The device name, including both the trade/proprietary name and classification name is provided below.

Product Name	Classification Name	Product Code	Regulation Number	Predicate Device Name	Date Predicate Cleared	Predicate 510(k)
OnTrak TesTcard 9	Amphetamines test system	91DKZ	862.3100	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	Barbiturates test system	91DIS	862.3150	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	Benzodiazepines test systems	91JXM	862.3170	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	Cocaine test systems	91DIO	862.3250	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	Methamphetamines test system	91LAF	862.3610	OnTrak TesTstik™ Methamphetamines	04/26/00	K000096
OnTrak TesTcard 9	Morphine test systems	91DJJ	862.3640	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	PCP test systems	91LCM	Not Assigned	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	Tricyclic antidepressants test systems	91LFG	862.3910	Triage® Panel	12/03/97	K973784
OnTrak TesTcard 9	Cannabinoid test systems	91LDJ	862.3870	Triage® Panel	12/03/97	K973784

3) Predicate device

We claim substantial equivalence to the currently marketed Biosite Diagnostics Triage® Panel Plus TCA (K973784) and the Roche Diagnostics Corporation, OnTrak TesTstik™ Methamphetamines (K000096).

---

4) Device Description

The OnTrak TesTcard 9 is an *in vitro* test intended for use by health care professionals only for the qualitative detection of drug or drug metabolites in urine. The OnTrak TesTcard 9 profile (cutoff) consists of amphetamines (1000 ng/ml), barbiturates (200 ng/ml), benzodiazepines (100 ng/ml), cocaine metabolite (300 ng/ml), methamphetamine (500 ng/ml), morphine (300 ng/ml), PCP (25 ng/ml), tricyclic antidepressants (1000 ng/ml) and THC (50 ng/ml).

The TesTcard 9 assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber.

When the TesTcard 9 contacts the urine sample, the sample is absorbed into the TesTcard 9 sample pad. The absorbed sample travels through the reagent strips contained in the device by capillary action. In the reagent strip, the sample rehydrates and mobilizes antibody-coated blue microparticles. The microparticle-urine suspension continues to migrate through the reagent strip and comes in contact with the immobilized drug conjugate. In the absence of drug in the urine, the antibody-coated microparticles bind to the drug conjugates and blue bands are formed in the result areas.

When drugs are present in the specimen, they bind to the respective antibody-coated microparticles. If sufficient drug is present, the microparticles are inhibited from binding the appropriate drug conjugate and no blue band is formed in the result area below the drug name. A positive sample causes the membrane to remain white.

An additional antibody/antigen reaction occurs at the "TEST VALID" area. The "TEST VALID" blue band forms when antibodies, imbedded in the reagent membrane, bind to the antigen on the blue microparticles. The presence of the "TEST VALID" band indicates that the test has completed, the reagents in the "TEST VALID" area are valid, and the results are ready to interpret.

---

5. Technology Characteristics

The TesTcard 9 assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber.

---

6. Substantial Equivalence

OnTrak TesTcard 9 is substantially equivalent to the currently marketed Biosite Diagnostics Triage® Panel Plus TCA (K973784) and the Roche Diagnostics Corporation, OnTrak TesTstik™ Methamphetamines (K000096). The following table describes the similarities and differences between the devices.

Item	OnTrak TesTcard 9	Triage® Panel	OnTrak TesTstik Methamphetamine
Methodology	Competitive microparticle capture inhibition	Competitive binding immunoassay	Same as TesTcard 9
Measurement	Qualitative	Same as TesTcard 9	Same as TesTcard 9
Sample Type	Urine	Same as TesTcard 9	Same as TesTcard 9
Cutoff	Amphetamines: 1000 ng/ml Barbiturates: 200 ng/ml Benzodiazepines: 100 ng/ml Cocaine metabolite: 300 ng/ml Methamphetamine: 500 ng/ml Morphine: 300 ng/ml PCP: 25 ng/ml TCA: 1000 ng/ml THC: 50 ng/ml	Amphetamines: 1000 ng/ml Barbiturates: 300 ng/ml Benzodiazepines: 300 ng/ml Cocaine: 300 ng/ml Opiates (Morphine): 300 ng/ml PCP: 25 ng/ml TCA: 1000 ng/ml THC: 50 ng/ml	Methamphetamine: 500 ng/ml
Reagent (active ingredients)	•Microparticles coated with mouse monoclonal anti-amphetamine and anti-barbiturate analogs, anti-benzoylecgonine, anti-methamphetamine, anti-morphine, anti-phencylidine, anti-TCA and anti-cannabinoid, sheep polyclonal anti-benzodiazepine analog and BSA in a buffered solution containing preservative and dried on a membrane. •Drug or drug analog conjugates immobilized on a membrane •Mouse monoclonal anti-BSA immobilized on membrane	• Mouse monoclonal antibodies against phencyclidine, benzodiazepine metabolites, benzoylecgonine, amphetamines, THC, morphine, barbiturates and tricyclic antidepressants immobilized on a membrane • Mouse monoclonal antibodies against phencyclidine, benzodiazepine metabolites, benzoylecgonine, amphetamines, THC, morphine, barbiturates and tricyclic antidepressants lyophilized in a protein matrix containing <0.01% sodium azide • Drugs and drug derivatives conjugated to colloidal gold, lyophilized in a protein matrix containing <0.01% sodium azide • Lyophilized buffer	• Mircroparticles coated with mouse monoclonal anti-methamphetamine antibody, and BSA in a buffered solution containing preservative and dried on a membrane. • Drug conjugates immobilized on a membrane. • Mouse monoclonal anti-BSA immobilized on a membrane.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 0 5 2001

Ms. Jennifer Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, In 46250-0457

Re: k012396
Trade/Device Name: Roche Diagnostics Corporation, OnTrak TesTcard 9
Regulation Number: 21 CFR 862.3100; 21 CFR 862.3150; 21 CFR 862.3170; 21 CFR 862.3250; 21 CFR 862.3610; 21 CFR 862.3640; Not Assigned; 21 CFR 862.3910; 21 CFR 862 3870
Regulation Name: Amphetamines test system; Barbiturates test system; Benzodiazepines test systems; Cocaine test systems; Methamphetamines test system; Morphine test systems; PCP test systems; Tricyclic antiepressants test Systems; Cannabinoid test systems
Regulatory Class: Class II; Class II; Class II; Class II; Class II; Class II; Class II; Class II; Class II
Product Code: DKZ; DIS; JXM; DIO; LAF; DJJ; LCM; LFG; LDJ
Dated: October 3, 2001
Received: October 4, 2001

Dear Ms. Tribbett:

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 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. 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 Part 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

NOV 0 5 2001

510(k) Number (if known): K012396
Device Name: Roche Diagnostics Corporation, OnTrak TesTcard 9

Indications for Use:

The Roche Diagnostics Corporation OnTrak TesTcard 9 is an in vitro diagnostic test intended for use by health care professionals only for the qualitative detection of drug or drug metabolites in urine. OnTrak TesTcard 9 simultaneously tests for the presence of multiple drugs or drug metabolites. The OnTrak TesTcard 9 profile (cutoff) consists of amphetamines (1000 ng/ml), barbiturates (200 ng/ml), benzodiazepines (100 ng/ml), cocaine metabolite (300 ng/ml), methamphetamine (500 ng/ml), morphine (300 ng/ml), PCP (25 ng/ml), tricyclic antidepressants (TCA-1000 ng/ml) and THC (50 ng/ml).

OnTrak TesTcard 9 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) is the preferred confirmation method. Clinical consideration and professional judgment should be applied to any drug abuse test result, particularly when preliminary positive results are used.

Dean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012396

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)