JAN 2 7 2000

K994030

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

Contact Person: Jennifer Tribbett

Date Prepared: November 24, 1999

2) Device name

Product Name	Classification Name	Product Code	CFR Classification
OnTrak TesTcup-5	Enzyme Immunoassay, Phencyclidine	91LCM	Unassigned

3) Predicate device

We claim substantial equivalence to the currently marketed Roche Diagnostics OnTrak TesTcup 5 (K964355).

4) Device Description

The OnTrak TesTcup-5 is an *in vitro* diagnostic test intended for professional use in the qualitative detection of amphetamines (1000ng/mL), cocaine metabolite (300 ng/mL), THC (50 ng/mL), morphine (300 ng/mL) and PCP (25 ng/mL).

The TesTcup 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.

Urine is collected directly in the OnTrak TesTcup-5 . After closing the cap and moving it to the "TEST" position, the sample reservoir is filled by tilting the cup. Urine then flows through a membrane by capillary action and reacts with antibody-coated microparticles and drug conjugate present on the membrane. In the absence of drug, the antibody is free to interact with the drug conjugate, causing the formation of a blue band ("negative" sign).

When drug is present in the specimen, it binds to the antibody-coated microparticles. If sufficient drug is present, the microparticles are inhibited from binding the drug conjugate, and no blue band is formed. A positive sample causes the membrane to remain white ("positive" sign).

An additional antibody/antigen reaction occurs at the "TEST VALID" area for all assays. The "TEST VALID" blue band forms when antibodies, which are imbedded in the membrane, interact with, and bind to, the antigen on the blue-dyed microparticles.

5. Technology Characteristics

Table 1 shown on the next page outlines the technological characteristics (methodologies) of the modified OnTrak TesTcup-5 in comparison to the predicate OnTrak TesTcup 5.

6. Substantial Equivalence

Table 1 also provides the results of evaluation studies performed using the modified OnTrak TesTcup-5 . The significant performance characteristics relied upon for a determination of substantial equivalence is summarized in this chart. This information concludes that the performance of the modified OnTrak TesTcup-5 device is substantially equivalent to the predicate device.

Table 1

Item	OnTrak TesTcup-5 New PCP Monoclonal Antibody	OnTrak TesTcup 5 Predicate
Methodology	Competitive microparticle capture inhibition	Same
Measurement	Qualitative	Same
Sample Type	Urine	Same
Endpoint read	Color	Same
PCP Cutoff	25 ng/mL	Same
Reagent (active ingredients)	•Blue dyed microparticles coated with mouse monoclonal antiphencyclidine. •Drug conjugates immobilized on a membrane •Mouse monoclonal anti-BSA antibody immobilized on membrane	•Blue dyed microparticles coated with rabbit polyclonal antiphencyclidine. •Drug conjugates immobilized on a membrane •Mouse monoclonal anti-BSA antibody immobilized on a membrane
Controls	OnTrak TesTcup Positive and Negative Controls	Same
Performance: Precision	>95% confidence at 150% cutoff	Same

Table 1 *(Continued)*

Item	OnTrak TesTcup-5 New PCP Monoclonal Antibody	OnTrak TesTcup 5 Predicate
PCP Performance: Accuracy	OnTrak TesTcup 5 was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at the 25 ng/mL cutoff. All ninety (90) of the PCP positive samples (100%) were positive by OnTrak TesTcup 5 . Three hundred seven (307) urine samples, obtained from a clinical laboratory and screened negative by an automated immunoassay relative to a 25 ng/mL cutoff for PCP were evaluated using OnTrak TesTcup 5. All three hundred seven (307) were negative for PCP (100%) All positive and negative samples were also assayed by, and compared to, Abuscreen OnLine for PCP. Three hundred ninety seven (397) samples tested by both OnTrak TesTcup 5 and Abuscreen OnLine for PCP demonstrated 100%	OnTrak TesTcup 5 was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at the 25 ng/mL cutoff. All ninety (90) of the PCP positive samples (100%) were positive by OnTrak TesTcup 5 . Three hundred seven (307) urine samples, obtained from a clinical laboratory and screened negative by an automated immunoassay relative to a 25 ng/mL cutoff for PCP were evaluated using OnTrak TesTcup 5. All three hundred seven (307) were negative for PCP (100%) All positive and negative samples were also assayed by, and compared to, Abuscreen OnTrak for PCP. Three hundred ninety seven (397) samples tested by both OnTrak TesTcup 5 and Abuscreen OnTrak for PCP demonstrated 100% agreement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 27 2000

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

Re: K994030
Trade Name: OnTrak TesTcup-5
Regulatory Class: II
Product Code: LCM
Dated: November 24 1999
Received: November 26, 1999

Dear Ms. Tribbett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

510(k) Number (if known):
Device Name: Roche Diagnostics Corporation, OnTrak TesTcup-5

Indications for Use:

OnTrak TesTcup® 5 is an in vitro diagnostic test intended for professional use for the qualitative detection of drug or drug metabolite in urine. OnTrak TesTcup 5 simultaneously tests for the presence of multiple drugs or drug metabolites.

The OnTrak TesTcup 5 profile (cutoff) consists of amphetamines (1000 ng/mL), cocaine metabolite (300 ng/mL), THC (50 ng/mL), morphine (300 ng/mL) and PCP (25 ng/mL).

OnTrak TesTcup 5 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 result, particularly when preliminary positive results are used.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994030

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

(Optional Format 1-2-96)