K994020

JAN 2 7 2000

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

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

Product Name	Classification Name	Product Code	CFR Classification Name	Predicate Device Name	Date Predicate Cleared	Predicate 510(k) Number
OnTrak TesTstik for PCP	Enzyme Immunoassay Phencyclidine	91LCM	Unassigned	OnTrak TesTstik for PCP	10/9/97	K973075

3) Predicate device

We claim substantial equivalence to the currently marketed Roche Diagnostics OnTrak TesTstik for PCP (K973075).

4) Device Description

The OnTrak TesTstik PCP assay contained in this submission is an *in vitro* diagnostic test intended for professional use in the qualitative detection of PCP in urine at or above a cutoff concentration of 25 ng/mL.

The TesTstik 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.

When the TesTstik is immersed in the urine sample, some of the sample is absorbed into the TesTstik sample pad. The absorbed sample travels through a reagent strip 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 conjugate and a blue band is formed at the result window ("negative" sign).

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

An additional antibody/antigen reaction occurs at the "TEST VALID" area. The "TEST VALID" blue band forms when antibodies, which are 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 are viable, and the results are ready to interpret.

5. Technology Characteristics

Table 1 on the next page outlines the technological characteristics (methodologies) of the OnTrak TesTstik for PCP in comparison to the predicate device.

510K Summary –*Continued-*

6. Substantial Equivalence

Table 1 provides the significant performance characteristics relied upon for a determination of substantial equivalence. This information concludes that the performance of the modified TesTstik PCP device is substantially equivalent to the currently marketed OnTrak TesTstik PCP (K973075).

TABLE 1

Item	OnTrak TesTstik for PCP New PCP Monoclonal Antibody	OnTrak TesTstik for PCP 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

510K Summary *–Continued-*

Item	OnTrak TesTstik for PCP New PCP Monoclonal Antibody	OnTrak TesTstik for PCP Predicate
PCP Performance: Accuracy	OnTrak TesTstik for PCP was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at the 25 ng/mL cutoff. Fifty (50) samples positive for PCP were positive by OnTrak TesTstik (100%). One hundred six (106) 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 and found negative using OnTrak TesTstik for PCP. All positive and negative samples were also assayed by, and compared to, Abuscreen OnLine for PCP. All samples demonstrated 100% agreement between the two assays.	OnTrak TesTstik for PCP was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at the 25 ng/mL cutoff. Fifty (50) samples positive for PCP were positive by OnTrak TesTstik (100%). One hundred six (106) 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 and found negative using OnTrak TesTstik. All positive and negative samples were also assayed by, and compared to, Abuscreen OnTrak for PCP. All samples demonstrated 100% agreement between the two assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 7 2000

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

Re: K994020
Trade Name: OnTrak TesTstik™ for PCP
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 TesTstik™ for PCP

Indications for Use:

The Roche Diagnostics Corporation OnTrak TesTstik™ for PCP is an *in vitro* diagnostic test intended for professional use for the qualitative detection of PCP in urine at or above a cutoff concentration of 25 ng/mL

OnTrak TesTstik provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994020

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)