

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: March 20, 2000

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™ 2 for Cocaine/ THC	Cocaine Test System	91DIO	862.3250	OnTrak TesTstik for Cocaine	10/9/97	K973075
OnTrak TesTstik™ 2 for Cocaine/ THC	Cannabinoid Test System	91LDJ	862.3870	OnTrak TesTstik for THC	10/9/97	K973075

3) Predicate device We claim substantial equivalence to the currently marketed Roche Diagnostics OnTrak TesTstik for Cocaine(K973075) and OnTrak TesTstik for THC (K973075).

4) Device Description

The OnTrak TesTstik 2 Cocaine/THC assay described in this submission is an *in vitro* test intended for professional use in the qualitative detection of cocaine metabolite and cannabinoids in urine at or above a cutoff concentration of 300 ng/ml (cocaine) and 50 ng/ml (THC).

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 conjugates and blue bands are 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.

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 in the TEST VALID area are viable, and the results are ready to interpret.

5. Technology Characteristics

Tables 1, 2 & 3 on the following pages outline the technological characteristics (methodologies) of the OnTrak TesTstik 2 for Cocaine/THC in comparison to the predicate devices.

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6. Substantial Equivalence

Tables 1, 2 & 3 provide the significant characteristics relied upon for a determination of substantial equivalence. This information concludes that the performance of the TesTstik 2 for Cocaine/THC is substantially equivalent to the currently marketed OnTrak TesTstik Cocaine (K973075) and OnTrak TesTstik THC (K973075).

TABLE 1

Item	OnTrak TesTstik 2 for Cocaine/THC New Device	OnTrak TesTstik for Cocaine Predicate	OnTrak TesTstik for THC Predicate
Methodology	Competitive microparticle capture inhibition	Same	Same
Measurement	Qualitative	Same	Same
Sample Type	Urine	Same	Same
Endpoint read	Color	Same	Same
Cutoff	300 ng/ml (cocaine) 50 ng/ml (THC)	Same 300 ng/ml (cocaine)	Same 50 ng/ml (THC)
Reagent (active ingredients)	<ul style="list-style-type: none"> •Blue dyed microparticles coated with mouse monoclonal anti-benzoylecgonine anti-body and anti-cannabinoid antibody. •Drug conjugates immobilized on a membrane •Mouse monoclonal anti-BSA antibody immobilized on membrane 	<ul style="list-style-type: none"> •Blue dyed microparticles coated with mouse monoclonal anti-benzoylecgonine antibody. •Drug conjugates immobilized on a membrane •Mouse monoclonal anti-BSA antibody immobilized on a membrane 	<ul style="list-style-type: none"> •Blue dyed microparticles coated with mouse monoclonal anti-cannabinoid antibody. •Drug conjugates immobilized on a membrane •Mouse monoclonal anti-BSA antibody immobilized on a membrane
Performance: Precision	>95% confidence at 150% cutoff	Same	Same

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Table 2

Item	OnTrak TesTstik 2 for Cocaine/THC	OnTrak TesTstik for Cocaine Predicate
Cocaine Performance: Accuracy	<p>OnTrak TesTstik 2 for Cocaine/THC was evaluated using clinical specimens screened by an automated immunoassay and confirmed positive by GC/MS. Seventy (70) specimens, including near cutoff specimens, positive for cocaine were evaluated on OnTrak TesTstik 2.</p> <p>One hundred urine specimens were obtained from a clinical laboratory and screened negative by automated immunoassays relative to a 300 ng/ml cutoff for cocaine. A portion (15%) of the negative specimens were also confirmed negative for cocaine by GC/MS. Clinical correlation for all positive (including near cutoff samples) and negative specimens was demonstrated as 94% agreement.</p>	<p>OnTrak TesTstik for Cocaine was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at a 150 ng/mL cutoff. Fifty (50) samples positive for cocaine were positive by OnTrak TesTstik (100%).</p> <p>One hundred six (106) urine samples, obtained from a clinical laboratory and screened negative by an automated immunoassay relative to a 300 ng/mL cutoff for cocaine were evaluated and found negative using OnTrak TesTstik.</p> <p>All positive and negative samples were also assayed by, and compared to, Abuscreen OnTrak for Cocaine. All samples demonstrated 100% agreement between the two assays.</p>

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Table 3

Item	OnTrak TesTstik 2 for Cocaine/THC	OnTrak TesTstik for THC Predicate
THC Performance: Accuracy	<p>OnTrak TesTstik 2 for Cocaine/THC was evaluated using clinical specimens screened by an automated immunoassay and confirmed positive by GC/MS. Seventy (70) specimens, including near cutoff specimens, positive for THC were evaluated on OnTrak TesTstik 2.</p> <p>One hundred urine specimens were obtained from a clinical laboratory and screened negative by automated immunoassays relative to a 50 ng/ml cutoff for THC. A portion (15%) of the negative specimens were also confirmed negative for THC by GC/MS. Clinical correlation for all positive (including near cutoff samples) and negative specimens was demonstrated as 95% agreement.</p>	<p>OnTrak TesTstik for THC was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at a 15 ng/mL cutoff. Forty five (45) samples positive for THC were positive by OnTrak TesTstik (100%).</p> <p>One hundred six (105) urine samples, obtained from a clinical laboratory and screened negative by an automated immunoassay relative to a 50 ng/mL cutoff for THC were evaluated and found negative using OnTrak TesTstik.</p> <p>All positive and negative samples were also assayed by, and compared to, Abuscreen OnTrak for THC. All samples demonstrated 100% agreement between the two assays.</p>



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2000

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

Re: K994164
Trade Name: OnTrak TesTstik™ 2 for Cocaine/THC
Regulatory Class: II
Product Code: LDJ, DIO
Dated: March 7, 2000
Received: March 8, 2000

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.

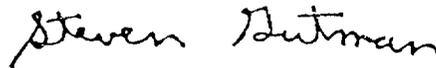
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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

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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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial "S" and "G".

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™ 2 for Cocaine/THC

Indications for Use:

OnTrak TesTstik 2 for Cocaine/THC is an in vitro diagnostic test intended for professional use for the qualitative detection of cocaine metabolite and cannabinoids in urine. The OnTrak TesTstik 2 for Cocaine/THC cutoff levels (300 ng/ml for cocaine and 50 ng/ml for THC) are based on the Federal Mandatory Guidelines. OnTrak TesTstik 2 for Cocaine/THC is not intended for over-the-counter sale.

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. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmation method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sean Cook

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number *R 994104*

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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