K990399

APR 15

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: March 22, 1999

2) Device Name

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

Product Name	Classification Name	Class	CFR Classification Name	Predicate Device Name	Date Predicate Cleared	Predicate 510(k) Number
OnTrak TesTstik for Morphine 2000 (M2K)	Morphine test system	II	862.3640	Abuscreen Online II for Opiates 300/2000	04/24/98	K974840

3) Predicate device

We claim substantial equivalence to the currently marketed Roche Diagnostics Abuscreen OnLine II for Opiates 300/2000 (K974840).

4) Device Description

The OnTrak TesTstik Morphine 2000 assay contained in this submission is an *in vitro* test intended for professional use in the qualitative detection of morphine in urine at or above a cutoff concentration of 2000 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.

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5. Technology Characteristics

Table 1 on the next pages outlines the technological characteristics (methodologies) of the OnTrak TesTstik for Morphine 2000 (M2K) in comparison to the Abuscreen OnLine II for Opiates 300/2000.

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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 TesTstik Morphine 2000 device is substantially equivalent to the currently marketed Abuscreen OnLine II for Opiates 300/2000 (K974840).

TABLE 1

Item	OnTrak TesTstik for Morphine 2000 (M2K)	Abuscreen Online for Opiates 2000
Methodology	Competitive microparticle capture inhibition	Kinetic interaction of microparticles
Measurement	Qualitative	Qualitative and Semi-Quantitative
Sample Type	Urine	Urine
Endpoint read	Color	Absorbance change
Cutoff	2000 ng/mL	2000 ng/mL
Reagent (active ingredients)	•Azo-blue dyed microparticles coated with mouse monoclonal anti-morphine antibody in a buffered solution with BSA and sodium azide. •Drug conjugates immobilized on a membrane •Mouse monoclonal anti-BSA antibody immobilized on membrane	•Microparticles coated with mouse monoclonal morphine antibody . •Morphine conjugated derivative in a buffer with BSA and sodium azide.
Controls	OnTrak TesTcup Positive and Negative Controls	Abuscreen OnLine Positive and Negative Controls
Performance: Precision	>95% confidence at 150% cutoff When one hundred (100) replicates of urine standards containing different concentrations of drug were tested with OnTrak TesTstik, the following results were found: Standard (ng/mL) — Morphine 2000 Assay: − / + 0: 100 / 0 500: 100 / 0 1000: 76 / 24 1500: 11 / 89 2500: 0 / 100 3000: 0 / 100	>95% confidence at 1.2 x (2400ng/mL) cutoff

510K Summary –*Continued*-

Table 1 –continued-

Performance: Accuracy	OnTrak TesTstik for Morphine 2000 (M2K) was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at the 2000 ng/mL cutoff. Fifty (50) samples positive for morphine were positive by OnTrak TesTstik M2K (100%). One hundred (100) urine samples, obtained from a clinical laboratory and screened negative by an automated immunoassay relative to a 2000 ng/mL cutoff for morphine were evaluated using OnTrak TesTstik M2K. One hundred (100) were negative for morphine by OnTrak TesTstik for Morphine 2000 (100%). All positive and negative samples were also assayed by, and compared to, Abuscreen OnLine II for Opiates 2000. One hundred fifty (150) samples, tested by both OnTrak TesTstik M2K and Abuscreen OnLine II for Opiates 2000, demonstrated 100% agreement.	Forty-two (42) samples shown to contain morphine and/or codeine by GC/MS above 2000 ng/mL were also positive in the Abuscreen OnLine II relative to the 2000 ng/mL cutoff (100% agreement) One hundred (100) urine samples, obtained from a clinical laboratory where they screened negative in a drug test panel, were evaluated with the Abuscreen OnLine II for Opiates 300/2000. All 100 samples were negative at both the 300 ng/mL and 2000 ng/mL cutoffs (100%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 1999

Jennifer L. Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250-0457

Re: K990399
Trade Name: OnTrak TesTcup M2K
Regulatory Class: II
Product Code: DKZ, DIO, DJJ, LDJ
Dated: February 5, 1999
Received: February 9, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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® M2K for Morphine 2000

Indications for Use:

OnTrak TesTcup® M2K is an *in vitro* test intended for professional use for the qualitative detection of drug or drug metabolite in urine. OnTrak TesTcup M2K simultaneously tests for the presence of multiple drugs or drug metabolites. The OnTrak TesTcup M2K cutoff levels are based on the Federal Mandatory Guidelines.

The OnTrak TesTcup M2K profile (cutoff) consists of d,l-amphetamines (1000 ng/mL), cocaine metabolite (300 ng/mL), THC (50 ng/mL) and morphine (2000 ng/mL).

OnTrak TesTcup M2K 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 K990399

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)