

APR 15 1999

K990409

## 510(k) Summary

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**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.

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**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

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**2) Device name**

Product Name	Classification Name	Class	CFR Classification
OnTrak TesTcup® M2K	Morphine test system	II	862.3640

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**3) Predicate device** We claim substantial equivalence to the currently marketed Roche Diagnostics OnTrak TesTcup (K962411).

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## 510(k) Summary, Continued

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### 4) Device Description

The OnTrak TesTcup M2K is an *in vitro* test intended for professional use in the qualitative detection of d,l-amphetamines (1000ng/mL), cocaine metabolite (300 ng/mL), THC (50 ng/mL) and morphine (2000 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 M2K. 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.

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### 5. Technology Characteristics

Table 1 shown on the next pages outlines the technological characteristics (methodologies) of the OnTrak TesTcup M2K in comparison to the predicate device, OnTrak TesTcup.

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### 6. Substantial Equivalence

Table 1 also provides the results of clinical and non-clinical studies performed using the OnTrak TesTcup M2K. 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 OnTrak TesTcup M2K device is substantially equivalent to the predicate device.

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510(k) Summary, Continued

**Table 1**

Item	OnTrak TesTcup M2K for Morphine 2000	OnTrak TesTcup																							
Methodology	Competitive microparticle capture inhibition	Same																							
Measurement	Qualitative	Same																							
Sample Type	Urine	Same																							
Endpoint read	Color	Same																							
Morphine Cutoff	2000 ng/mL	300 ng/mL																							
Reagent (active ingredients)	<ul style="list-style-type: none"> <li>•Azo-blue dyed microparticles coated with mouse monoclonal anti-morphine antibody</li> <li>•Drug conjugates immobilized on a membrane</li> <li>•Mouse monoclonal anti-BSA antibody immobilized on membrane</li> </ul>	Same																							
Controls	OnTrak TesTcup Positive and Negative Controls	Same																							
Performance: Precision	<p>&gt;95% confidence at 150% cutoff</p> <p>When one hundred (100) replicates of urine standards containing different concentrations of drug were tested with OnTrak TesTcup, the following results were found:</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th rowspan="2">Standard (ng/mL)</th> <th colspan="2">Morphine 2000 Assay</th> </tr> <tr> <th>=</th> <th>±</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>100</td> <td>0</td> </tr> <tr> <td>500</td> <td>100</td> <td>0</td> </tr> <tr> <td>1000</td> <td>98</td> <td>2</td> </tr> <tr> <td>1500</td> <td>60</td> <td>40</td> </tr> <tr> <td>2500</td> <td>0</td> <td>100</td> </tr> <tr> <td>3000</td> <td>0</td> <td>100</td> </tr> </tbody> </table>	Standard (ng/mL)	Morphine 2000 Assay		=	±	0	100	0	500	100	0	1000	98	2	1500	60	40	2500	0	100	3000	0	100	>95% confidence at 150% cutoff
Standard (ng/mL)	Morphine 2000 Assay																								
	=	±																							
0	100	0																							
500	100	0																							
1000	98	2																							
1500	60	40																							
2500	0	100																							
3000	0	100																							

510(k) Summary, Continued

TABLE 1 –Continued–

Item	OnTrak TesTcup M2K for Morphine 2000	OnTrak TesTcup
<p>Morphine Performance: Accuracy</p>	<p>OnTrak TesTcup M2K was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at 2000 ng/mL cutoff. All fifty (50) samples positive for morphine were positive by OnTrak TesTcup M2K (100%).</p> <p>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 TesTcup M2K. All one hundred were negative for morphine by OnTrak TesTcup M2K (100%).</p> <p>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 TesTcup M2K and Abuscreen OnLine II for Opiates 2000 demonstrated 99.3% agreement.</p>	<p>OnTrak TesTcup was evaluated using specimens screened by an automated immunoassay and confirmed positive by GC/MS at the 300 ng/mL cutoff. All ninety (90) samples positive for morphine were positive by OnTrak TesTcup (100%).</p> <p>Three hundred seven (307) urine samples, obtained from a clinical laboratory and screened negative by an automated immunoassay relative to a 300 ng/mL cutoff for morphine were evaluated using OnTrak TesTcup. Three hundred five were negative for morphine by OnTrak TesTcup (&gt;99%).</p> <p>All positive and negative samples were also assayed by, and compared to, Abuscreen OnTrak for Morphine. Three hundred ninety seven (397) samples tested by both OnTrak TesTcup and Abuscreen OnTrak for Morphine demonstrated 99.8% agreement.</p>



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K990409  
Trade Name: OnTrak TesTstik M2K  
Regulatory Class: II  
Product Code: DJJ, DMY  
Dated: January 25, 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.

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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 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 Morphine 2000 (M2K)

Indications for Use:

The Roche Diagnostics Corporation OnTrak TesTstik™ for Morphine 2000 (M2K) is an *in vitro* test intended for professional use for the qualitative detection of morphine in urine at or above a cutoff concentration of 2000 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 K990409

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)