

2/26/99

K990377

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: February 3, 1999

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

Product Name	Common Name	Regulation Number	Classification Name	Class	Product Code
OnTrak TesTcup M2K and OnTrak TesTstik Controls	Clinical toxicology control material	862.3280	Drug mixture control material	I	DIF

3) Predicate device We claim substantial equivalence to the currently marketed OnTrak TesTcup/OnTrak TesTstik Controls as well as the Synchron Systems DAT Low Urine Control II and DAT High Urine Control II.

4) Device Description The OnTrak TesTcup M2K/OnTrak TesTstik Controls are quality control samples for use with the OnTrak TesTcup M2K and OnTrak TesTstik systems for amphetamine, barbiturates, benzodiazepines, cocaine, morphine 2000 (M2K), phencyclidine (PCP) and THC.

Continued on next page

510(k) Summary, Continued

5. Technology Characteristics

The OnTrak TesTcup M2K/OnTrak TesTstik Controls are prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Preservatives and stabilizers are added to maintain product integrity.

6. Substantial Equivalence

The modified OnTrak TesTcup M2K/OnTrak TesTstik Controls are substantially equivalent to the currently marketed OnTrak TesTcup/OnTrak TesTstik Controls as well as the Synchron Systems DAT Low Urine Control II and DAT High Urine Control II.

The OnTrak TesTcup and TesTstik Control was previously cleared on October 9, 1998 (K983387).

This Premarket Notification [510(k)] is being submitted to the agency due to the Department of Health and Human Services Substance Abuse and Mental Health Services Administration's (SAMHSA) revision in the recommended cutoff for morphine. The cutoff was previously 300 ng/mL, but SAMHSA is currently recommending 2000 ng/mL. Therefore, the level of morphine in the corresponding positive controls must also change to capture the higher cutoff value. This notification addresses the change in the positive control morphine level from 750 ng/mL to 5000 ng/mL.

In addition, this notification also addresses the addition of oxazepam as a new constituent.

The current cutoff levels for the OnTrak TesTcup and TesTstik assays are:

Amphetamines: 1000 ng/mL
Cannabinoids: 50 ng/mL
Cocaine: 300 ng/mL
Morphine: 2000 ng/mL
Phencyclidine: 25 ng/mL
Secobarbital: 200 ng/mL
Oxazepam: 200 ng/mL

A summary of the similarities and differences between the OnTrak TesTcup M2K/OnTrak TesTstik Controls and the predicate products is listed in Table 1 and Table 2.

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510(k) Summary, Continued

Table 1

	Modified OnTrak TesTcup M2K and TesTstik Controls		Current OnTrak TesTcup and TesTstik Controls	
	Negative	Positive	Negative	Positive
Matrix	Human urine	Human urine	Human urine	Human urine
Drugs:	ng/mL	ng/mL	ng/mL	ng/mL
Amphetamines	0	2500	0	2500
Cannabinoids	0	125	0	125
Cocaine	0	750	0	750
Morphine	0	5000	0	750
Phencyclidine	0	62.5	0	62.5
Secobarbital	0	500	0	500
Oxazepam	0	500	NA	NA

510(k) Summary, Continued

**6. Substantial
Equivalence**
(Continued)

The predicate device for the oxazepam constituent is the Beckman Synchron systems DAT Low and High Urine Controls II. The table below indicates drug concentrations found in the Beckman Controls II.

Beckman Synchron Systems DAT Low and High Urine Controls II		
	Low Urine Control II	High Urine Control II
Matrix	Human urine	Human urine
Drugs:	ng/mL	ng/mL
Secobarbital (Barbiturates)	150	300
Oxazepam (Benzodiazepine)	150	300
Methadone	200	375
Methaqualone	200	375
Propoxyphene	200	375

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FEB 26 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K990377
Trade Name: OnTrack TesTcup M2K and OnTrack TesTstik Positive Control
Regulatory Class: I
Product Code: DIF
Dated: February 3, 1999
Received: February 8, 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 (Pre-market 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 TesTcup M2K/OnTrak TesTstik Controls

Indications for Use:

The Roche Diagnostics Corporation OnTrak TesTcup M2K/OnTrak TesTstik Controls are quality control samples for use with the OnTrak TesTcup M2K and OnTrak TesTstik systems for amphetamine, barbiturates, benzodiazepines, cocaine, morphine 2000 (M2K), phencyclidine (PCP) and THC.

[Signature]
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K990377

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)

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