K033902

JAN 2 0 2004

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

Varian, Inc.
25200 Commercentre Drive
Lake Forest, CA 92630
(949) 770-9381

Contact: Lorna Gamboa

Date Prepared: December 15, 2003

2) Device Name

Proprietary Name: OnTrak TesTcup® II and OnSite CupKit™

Panel: Toxicology

Classification Name:	Product Code	Regulation Number
Enzyme Immunoassay, Amphetamine	DKZ	862.3100
Enzyme Immunoassay, Benzodiazepine	JXM	862.3170
Enzyme Immunoassay, Cocaine and Cocaine Metabolite	DIO	862.3250
Enzyme Immunoassay, Opiate	DJG	862.3650
Enzyme Immunoassay, Phencyclidine	LCM	Unclassified
Enzyme Immunoassay, Cannabinoids	LDJ	862.3870
Thin Layer Chromatography, Methamphetamine	DJC	862.3610

3) Predicate Device

We claim substantial equivalence to these currently marketed devices:

OnTrak TesTcup® 501, K001421, 7/12/2000
OnTrak TesTcup 5 M2K, K994017, 1/27/2000
OnTrak TesTstik BNZ, K983174, 11/18/98
OnTrak TesTstik® 2 COC/THC, K994164, 4/13/2000

4) Device Description

The OnTrak TesTcup II and OnSite Cupkit assays contained in this submission are in vitro diagnostic tests intended for professional use for the qualitative detection of amphetamines (d,l-amphetamine 1000 ng/mL), benzodiazepines (oxazepam 200 ng/mL), cocaine metabolite (benzoylecgonine 300 ng/mL), methamphetamine (d-methamphetamine 500 ng/mL), morphine (morphine 300 ng/mL) and morphine 2000 (morphine 2000 ng/mL), PCP (phencyclidine 25 ng/mL), and THC (11-nor-Δ^9-THC-9-carboxylic acid 50 ng/mL).

The 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 test cup provided. The drug profile card is placed in the samples by inserting it into the lid holder, then securing the lid onto the cup. Urine is drawn in the profile card 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. 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 at the result window. A preliminary positive ("non-negative" result is the absence of a blue band). An additional antibody/antigen reaction occurs at the "VALID" area. The "VALID" blue band forms when antibodies, which are imbedded in the reagent membrane, interact with and bind to the antigen on the blue microparticles.
5) Statement of Intended Use	OnTrak TesTcup II and OnSite Cupkit assays are intended for professional use for the qualitative detection of amphetamines (d,l-amphetamine 1000 ng/mL), benzodiazepines (oxazepam 200 ng/mL), cocaine metabolite (benzoylecgonine 300 ng/mL), methamphetamine (d-methamphetamine 500 ng/mL), morphine (morphine 300 ng/mL) and morphine 2000 (morphine 2000 ng/mL), PCP (phencyclidine 25 ng/mL), and THC (11-nor-Δ^9-THC-9-carboxylic acid 50 ng/mL).
6) Technological Characteristics	See "Summary of Testing" on the following pages.
Substantial Equivalence	The TesTcup II and CupKit devices have the same intended use and incorporate the same fundamental scientific technology as the predicate devices.

Summary of testing

Precision

The precision of TesTcup II and CupKit was determined by three operators across three different days, who tested 63 replicates on two lots using contrived specimens containing drugs or drug metabolites at various concentrations. The drug or drug metabolites were spiked into negative human urine pool and assayed by GC/MS. The results are summarized in the tables below.

All lots are required minimally to perform with a greater than 95% confidence level that negative results will be attained with drugs at 25% (1/4 X) of their respective cutoff concentrations, and a greater than 95% confidence level that positive results will be attained with drugs at 150% (1/-1/2 X) of their respective cutoff concentrations.

Amphetamine (ng/ml) Cutoff = 1000 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
250	0	100	0	100
500	12.7	87.3	4.8	95.2
750	93.6	6.4	88.9	11.1
1250	100	0	100	0
1500	100	0	100	0

Morphine (ng/ml) Cutoff = 2000 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
500	0	100	0	100
1000	6.3	93.7	0	100
1500	80.9	19.1	31.7	68.3
2500	100	0	100	0
3000	100	0	100	0

PCP (ng/ml) Cutoff = 25 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
6.25	0	100	0	100
12.5	0	100	0	100
18.75	4.7	95.3	6.3	93.7
31.25	95.2	4.8	100	0
37.5	100	0	100	0

Benzodiazepines (ng/ml) Cutoff = 200 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
50	0	100	0	100
100	6.3	93.7	22.2	77.8
150	49.2	50.8	46	54
250	100	0	100	0
300	100	0	100	0

Cocaine (ng/ml) Cutoff = 300 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
75	0	100	0	100
150	55.6	44.4	19	81
225	100	0	93.7	6.3
375	100	0	100	0
450	100	0	100	0

THC (ng/ml) Cutoff = 50 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
12.5	0	100	0	100
25	0	100	0	100
37.5	0	100	9.5	90.5
62.5	96.8	3.2	100	0
75	100	0	100	0

Morphine (ng/ml) Cutoff = 300 ng/ml	Precision Results (%)			
	Lot 1		**Lot 2**	
	+	-	+	-
0	0	100	0	100
75	0	100	0	100
150	0	100	0	100
225	17.5	82.5	1.6	98.4
375	100	0	100	0
450	100	0	100	0

Methamphetamine(ng/ml) Cutoff = 500 ng/ml	Precision Results (%)			
	Lot 1		Lot 2	
	+	-	+	-
0	0	100	0	100
125	0	100	0	100
250	6.3	93.7	0	100
375	79.4	20.6	66.7	33.3
625	100	0	100	0
750	100	0	100	0

Specificity

The following structurally similar compounds for amphetamine, benzodiazepines, cocaine, methamphetamine, morphine, PCP and THC were tested for cross reactivity with TesTcup II/CupKit. Each compound tested was prepared in normal human urine. The results are expressed as that amount of the compound capable of giving a result equivalent to the cutoff for that assay.

Amphetamine-related Compounds	**Minimum Concentration Required to give a positive result (ng/ml)**
d-Amphetamine	500
Methylenedioxyamphetamine (MDA)	5000
l-Amphetamine	25,000
β-Phenethylamine	100,000
d,l-Phenylpropanolamine	100,000
d,l-Methamphetamine	>100,000

Benzodiazepines-related Compounds	**Minimum Concentration Required to give a positive result (ng/ml)**
7-Aminoflunitrazepam	100
Bromazepam	100
Didesethylflurazepam	100
7-Aminonitrazepam	100
α-Hydroxyalprazolam	100
α-Hydroxytriazolam	100
Norfludiazepam	100
Nordiazepam	100
Temazepam	100
Clonazepam	250
Lorazepam	250
Chlorazepate	250
Flurazepam	250
Desmethylflunitrazepam	250
Alprazolam	250
Diazepam	250
Demoxepam	500

Triazolam	500
Hydroxyethylflurazepam	1000
Flunitrazepam	1000
Chlordiazepoxide	2000

Cocaine-related Compounds	**Minimum Concentration Required to give a positive result (ng/ml)**
Cocaine HCl	>100,000

Methamphetamine-related Compounds	**Minimum Concentration Required to give a positive result (ng/ml)**
Propylhexedrine	1000
d,l-Methamphetamine	2000
3,4-Methylenedioxymethamphetamine (MDMA)	2000
l-Methamphetamine	3000
Fenfluramine	5000
p-Hydroxymethamphetamine	5000
3,4-Methylenedioxyethylamphetamine (MDEA)	10,000
d-Amphetamine	25,000
l-Phenylephrine	50,000
d,l-Ephedrine	50,000
Ranitidine	50,000
β-Phenethylamine	50,000
d,l-Amphetamine	50,000
3,4-Methylenedioxyamphetamine (MDA)	100,000
l-Amphetamine	>100,000

Morphine-300-related Compounds	**Minimum Concentration Required to give a positive result (ng/ml)**
Codeine	250
Ethyl morphine HCl	250
Dihydrocodeine bitartrate	500
6-Acetylmorphine	500
Hydrocodone bitartrate	500
Morphine-3-glucuronide	500
Hydromorphone HCl	1000
Nalorphine	2000
Thebaine	3000
Levorphanol	25,000
Rifampin	50,000
N-Norcodeine HCl	100,000
Oxycodone	100,000
Meperidine	100,000
Atropine	>100,000

THC-related Compounds	**Minimum Concentration Required to give a positive result (ng/ml)**
11-hydroxy - Δ^9 THC	50,000

Morphine-2000-related Compounds	Minimum Concentration Required to give a positive result (ng/ml)
Codeine	2000
6-Acetylmorphine	2000
Ethyl morphine HCl	3000
Dihydrocodeine bitartrate	3000
Morphine-3-glucuronide	3000
Hydrocodone bitartrate	10,000
Hydromorphone HCl	10,000
Nalorphine	25,000
Thebaine	50,000
Levorphanol	>100,000
Rifampin	>100,000
Oxycodone	>100,000

Cross-Reactivity with Additional Drugs

The following compounds were tested at 100,000 ng/ml and found not to cross-react with the (OnTrak TesTcup II or Onsite CupKit) assays (except as noted).

Acetominophen
Acetylsalicylic acid
6-Acetylmorphine (except morphine assay)
Alprazolam (except benzodiazepine assay)
7-Aminoflunitrazepam (except benzodiazepine assay)
7-Aminonitrazepam (except benzodiazepine assay)
d,l-Amphetamine (except amphetamine and methamphetamine assay)
d-Amphetamine (except amphetamine and methamphetamine assay)
l-Amphetamine (except amphetamine and methamphetamine assay)
Atropine
Benzocaine
Benzphetamine
Bromazepam (except benzodiazepine assay)
(±) Brompheniramine
Buprenorphine
Bupropion
Chlorazepate (except benzodiazepine assay)
Chlordiazepoxide (except benzodiazepine assay)
Clonazepam (except benzodiazepine assay)
Cocaine HCl (except Cocaine assay)
Codeine (except morphine assay)
Demoxepam (except benzodiazepine assay)
Desmethylflunitrazepam (except benzodiazepine assay)
Dextromethorphan
Dextrorphan
Diazepam (except benzodiazepine assay)
Didesethylflurazepam (except benzodiazepine assay)
Dihydrocodeine bitartrate (except morphine assay)
Diphenhydramine
d,l-Methamphetamine (except methamphetamine assay)

Doxylamine
d,l-Ephedrine (except methamphetamine assay)
Ethyl morphine HCl (except morphine assay)
Fenfluramine (except methamphetamine assay)
Fenoprofen
Flunitrazepam (except benzodiazepine assay)
Flurazepam (except benzodiazepine assay)
Gemfibrozil
Hydrochlorothiazide
Hydrocodone bitartrate (except morphine assay)
Hydromorphone HCl (except morphine assay)
α-Hydroxyalprazolam (except benzodiazepine assay)
Hydroxybupropion
Hydroxyethylflurazepam (except benzodiazepine assay)
p-Hydroxymethamphetamine (except methamphetamine assay)
α-Hydroxytriazolam (except benzodiazepine assay)
Ibuprofen
Ketamine
Lansoprazole
Levorphanol (except morphine assay)
Lidocaine
Lorazepam (except benzodiazepine assay)
MDA (except amphetamine and methamphetamine assay)
MDEA (except methamphetamine assay)
MDMA (except methamphetamine assay)
Meperidine (except morphine assay)
d-Methamphetamine (except methamphetamine assay)
d,l-Methamphetamine (except amphetamine and methamphetamine assay)
l-Methamphetamine (except methamphetamine assay)
Methylphenidate
Morphine-3-glucuronide (except morphine assay)
Nalorphine (except morphine assay)
Naproxen
N-Norcodeine HCl (except morphine assay)
Nordiazepam (except benzodiazepine assay)
Norfludiazepam (except benzodiazepine assay)
Oxycodone (except morphine assay)
β-Phenethylamine (except amphetamine and methamphetamine assay)
l-Phenylephrine (except methamphetamine assay)
d,l-Phenylpropanolamine (except amphetamine assay)
Propylhexedrine (except methamphetamine assay)
Quinidine
Quinine
Ranitidine (except methamphetamine assay)
Rifampin (except morphine assay)
Temazepam (except benzodiazepine assay)
Thebaine (except morphine assay)
11-hydroxy - Δ^9 THC (except THC assay)
Δ^9 THC
Triazolam (except benzodiazepine assay)

Accuracy

TesTcup II and CupKit was evaluated in a SAMHSA certified laboratory using clinical specimens. The clinical negative samples were screened negative by an automated immunoassay and reported as negative according to SAMHSA guidelines. Clinical specimens screened positive by an automated immunoassay were subsequently analyzed by GC/MS. Some samples were diluted with negative human urine to achieve the appropriate test range. Results are summarized below.

Comparison with Reference Method (GC/MS):

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
THC Cutoff = 50 ng/ml	+	0	13	6	31
	-	100	0	0	0

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
Cocaine Cutoff = 300 ng/ml	+	0	6	7	35
	-	100	1	1	0

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
PCP Cutoff = 25 ng/ml	+	0	2	3	37
	-	100	8	0	0

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
Amphetamine Cutoff = 1000 ng/ml	+	0	6	5	29
	-	100	8	0	2*

*GC/MS values for these samples were 1569 ng/mL and 1776 ng/mL.

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
Methamphetamine Cutoff = 500 ng/ml	+	0	3	5	48
	-	100	2	0	0

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
Morphine Cutoff = 300 ng/ml	+	0	7	8	46
	-	100	0	0	0

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
Morphine (M2K) Cutoff = 2000 ng/ml	+	0	7	5	35
	-	100	3	0	0

		Negative Samples	GC/MS Values (ng/ml)		
			Near Cutoff		> 125% of cutoff
			75% to 100% of Cutoff	100% to 125% of cutoff	
Benzodiazepines Cutoff = 200 ng/ml	+	0	6	8	50
	-	100	0	0	0

Comparison with predicate device

All of the above clinical specimens were also tested by, and results compared to, OnTrak TesTcup and OnTrak TesTstik. Results are summarized below.

THC Overall percent agreement = 98%		TesTstik 2	
		+	-
New Test	+	47	3
	-	0	100

Cocaine Overall percent agreement = 100%		TesTstik 2	
		+	-
New Test	+	48	0
	-	0	102

PCP Overall percent agreement = 99%		TesTstik 2	
		+	-
New Test (CupKit)	+	41	1
	-	0	108

Amphetamines Overall percent agreement = 97%		TesTstik 2	
		+	-
New Test	+	36	4
	-	0	110

Methamphetamine Overall percent agreement = 100%		TesTstik 2	
		+	-
New Test	+	56	0
	-	0	102

Morphine Overall percent agreement = 100%		TesTstik 2	
		+	-
New Test	+	61	0
	-	0	100

Morphine 2000 (M2K) Overall percent agreement = 96%		TesTstik 2	
		+	-
New Test	+	41	6
	-	0	103

Benzodiazepines Overall percent agreement = 100%		TesTstik 2	
		+	-
New Test	+	64	0
	-	0	100

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 0 2004

Ms. Lorna Gamboa
Regulatory Affairs Manager
Varian, Inc.
25200 Commercentre Drive
Lake Forest, CA 92630

Re: k033902
Trade/Device Name: On Trak TesTcup® II and OnSite CupKit™
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: January 13, 2004
Received: January 14, 2004

Dear Ms. Gamboa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K033902

Device Name: OnTrak TesTcup® II and OnSite CupKit™

Indications for Use:

TesTcup II and CupKit products are in vitro diagnostics tests intended for professional use for the qualitative detection of drugs or drug metabolites in urine at or above the stated cutoff concentrations.

Cutoff Concentrations:

Amphetamines:	1000 ng/mL	Morphine:	300 ng/mL
Benzodiazepines:	200 ng/mL	Morphine (M2K):	2000 ng/mL
Cocaine metabolite:	300 ng/mL	Phencyclidine (PCP):	25 ng/mL
Methamphetamine:	500 ng/mL	Tetrahydrocannabinols (THC):	50 ng/mL

TesTcup II and CupKit products provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert Cutler for Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033902

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____