OCT - 9 1997

Roche Diagnostic Systems
A Member of the Roche Group

Roche Diagnostic Systems, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Direct Dial
Fax

K973075

510(k) Summary

ONTRAK TESTSTIK Assays

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary is provided as outlined in 21 CFR 807.92.

I. Identification of 510(k) Sponsor:

Roche Diagnostic Systems, Inc.
a subsidiary of Hoffmann-La Roche, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

510(k) Submission dated August 15, 1997

Contact: James W. Haynes
Regulatory Affairs Associate
Phone: (908) 253-7569
Fax: (908) 253-7547

II. Device Name:

The device name, including both the trade/proprietary name and the classification name are provided in the table below.

Table 1

Proprietary Name	Classification Name	Regulation Number
ONTRAK TESTSTIK for...		
Amphetamines	Amphetamines test system	862.3100
Cocaine	Cocaine test system	862.3250
Morphine	Morphine test system	862.3640
PCP	Phencyclidine test system	NA
THC	Cannabinoid test system	862.3870

III. Identification of the legally marketed device to which the 510(k) sponsor claims equivalence:

The following table identifies the legally marketed devices to which Roche Diagnostic Systems, Inc. claims equivalence.

Table 2

Proprietary Name	Predicate Product Name	K number	Date of substantial equivalence
ONTRAK TESTSTIK for...			
Amphetamines	Abuscreen ONTRAK for Amphetamines	K881817/A	7/29/88
Cocaine	Abuscreen ONTRAK for Cocaine	K881815	7/29/88
Morphine	Abuscreen ONTRAK for Morphine	K882496	9/2/88
PCP	Abuscreen ONTRAK for PCP	K895906	1/26/90
THC	Abuscreen ONTRAK for THC	K904856	12/13/90

IV. Description of the Device/Statement of Intended Use:

The 5 ONTRAK TESTSTIK Assays contained in this submission are *in vitro* diagnostic tests intended for professional use for the qualitative detection of drug or drug metabolite in urine. They are the ONTRAK TESTSTIK for Amphetamines (1000 ng/mL cutoff), the ONTRAK TESTSTIK for Cocaine (300 ng/mL cutoff), the ONTRAK TESTSTIK for THC (50 ng/mL cutoff), the ONTRAK TESTSTIK for Morphine (300 ng/mL cutoff) and the ONTRAK TESTSTIK for PCP (25 ng/mL cutoff).

The ONTRAK TESTSTIK Assays are based on the principle of microparticle capture inhibition. These tests rely on the competition between the specific drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane test chamber.

When an ONTRAK 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 particles, the microparticles are inhibited from binding the drug conjugate and no blue band is formed at the result window. Therefore, a positive sample causes 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 embedded in the reagent membrane, bind to the antigen on the blue microparticles.

V. Summary of the technological characteristics of the new device in comparison to those of the predicate.

Tables 3-7 outline the technological characteristics (methodologies) of the ONTRAK TESTSTIK Assays in comparison to those of legally marketed predicate products.

VI. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence:

Tables 3-7 demonstrate the results of clinical and nonclinical studies performed using the ONTRAK TESTSTIK Assays. The significant performance characteristics relied upon for a determination of substantial equivalence are summarized in this chart. This information concludes that the performance of these devices are essentially equivalent to other legally marketed devices of a similar kind.

Table 3 - ONTRAK TESTSTIK for Amphetamines

	ONTRAK TESTSTIK for Amphetamines				**Abuscreen ONTRAK for Amphetamines**
Methodology	Competitive microparticle capture inhibition				Competitive latex agglutination inhibition
Measurement	Qualitative				Qualitative
Sample type	urine				urine
Endpoint read	color				agglutination pattern
Cutoff(s)	1000 ng/mL				1000 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with mouse monoclonal anti-amphetamine analogue 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA antibody immobilized on a membrane				1. Sheep anti-amphetamine antibody in a buffered solution 2. Reaction buffer 3. Latex-amphetamine conjugate in a buffered solution
Controls	ONTRAK TESTCUP Positive & Negative Controls				Abuscreen ONTRAK for Amphetamines Negative Control
Performance Characteristics:					
Precision	> 95% confidence at 150% cutoff				> 99% confidence at 200% of cutoff
Accuracy: Positive Samples		TesTstik	ONTRAK	GC/MS	GC/MS
	+	50	50	50	45
	-	0	0	0	1

Table 4 - ONTRAK TESTSTIK for Cocaine

	ONTRAK TESTSTIK for Cocaine				**Abuscreen ONTRAK for Cocaine**
Methodology	Competitive microparticle capture inhibition				Competitive latex agglutination inhibition
Measurement	Qualitative				Qualitative
Sample type	urine				urine
Endpoint read	color				agglutination pattern
Cutoff(s)	300 ng/mL				300 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with mouse monoclonal anti-benzoylecgonine antibody 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA antibody immobilized on a membrane				1. Mouse monoclonal anti-benzoylecgonine antibody in a buffered solution 2. Reaction buffer 3. Latex- benzoylecgonine conjugate in a buffered solution
Controls	ONTRAK TESTCUP Positive & Negative Controls				Abuscreen ONTRAK for Cocaine Negative Control
Performance Characteristics:					
Precision	> 95% confidence at 150% cutoff				> 99% confidence at 200% of cutoff
Accuracy: Positive Samples		TESTSTIK	ONTRAK	GC/MS	GC/MS
	+	50	50	50	49
	-	0	0	0	0

Table 5 - ONTRAK TESTSTIK for Morphine

	ONTRAK TESTSTIK for Morphine	**Abuscreen ONTRAK for Morphine**
Methodology	Competitive microparticle capture inhibition	Competitive latex agglutination inhibition
Measurement	Qualitative	Qualitative
Sample type	urine	urine
Endpoint read	color	agglutination pattern
Cutoff(s)	300 ng/mL	300 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with mouse monoclonal anti-morphine antibody 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA antibody immobilized on a membrane	1. Mouse anti- morphine antibody in a buffered solution 2. Reaction buffer 3. Latex-morphine conjugate in a buffered solution
Controls	ONTRAK TESTCUP Positive & Negative Controls	Abuscreen ONTRAK for Morphine Negative Control
Performance Characteristics:		
Precision	> 95% confidence at 150% cutoff	> 99% confidence at 200% of cutoff

Accuracy: Positive Samples		TESTSTIK	ONTRAK	GC/MS	GC/MS
	+	49	50	50	54
	-	1	0	0	0

Table 6 - ONTRAK TESTSTIK for PCP

	ONTRAK TESTSTIK for PCP				**Abuscreen ONTRAK for PCP**
Methodology	Competitive microparticle capture inhibition				Competitive latex agglutination inhibition
Measurement	Qualitative				Qualitative
Sample type	urine				urine
Endpoint read	color				agglutination pattern
Cutoff(s)	25 ng/mL				25 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with rabbit polyclonal anti-phencyclidine antibody 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA antibody immobilized on a membrane				1. Rabbit anti- phencyclidine antibody in a buffered solution 2. Reaction buffer 3. Latex- phencyclidine conjugate in a buffered solution
Controls	ONTRAK TESTCUP Positive & Negative Controls				Abuscreen ONTRAK for PCP Negative Control
Performance Characteristics:					
Precision	> 95% confidence at 150% cutoff				> 99% confidence at 200% of cutoff
Accuracy: Positive Samples		TESTSTIK	ONTRAK	GC/MS	GC/MS
	+	50	50	50	52
	-	0	0	0	1

Table 7 - ONTRAK TESTSTIK for THC

	ONTRAK TESTSTIK for THC				Abuscreen ONTRAK for THC
Methodology	Competitive microparticle capture inhibition				Competitive latex agglutination inhibition
Measurement	Qualitative				Qualitative
Sample type	urine				urine
Endpoint read	color				agglutination pattern
Cutoff(s)	50 ng/mL				50 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with mouse monoclonal anti-cannabinoid antibody 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA antibody immobilized on a membrane				1. Mouse monoclonal anti-cannabinoid in a buffered solution 2. Reaction buffer 3. Latex-tetrahydrocannabinoid conjugate in a buffered solution
Controls	ONTRAK TESTCUP Positive & Negative Controls				Abuscreen ONTRAK for THC Negative Control
Performance Characteristics:					
Precision	> 95% confidence at 150% cutoff				> 99% confidence at 200% of cutoff
Accuracy: Positive Samples		TESTSTIK	ONTRAK	GC/MS	GC/MS
	+	45	45	45	50
	-	0	0	0	0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. James W. Haynes
Regulatory Affairs Associate
Roche Diagnostic Systems, Inc.
a subsidiary of Hoffmann-La Roche, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

OCT - 9 1997

Re: K973075
Trade Name: OnTrak TesTstik Assays
Regulatory Class: II
Product Code: DKZ
Dated: August 15, 1997
Received: August 18, 1997

Dear Mr. Haynes:

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 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 requirement, 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) K973075

Device Name: ONTRAK TESTSTIK for Amphetamines
ONTRAK TESTSTIK for Cocaine
ONTRAK TESTSTIK for Morphine
ONTRAK TESTSTIK for PCP
ONTRAK TESTSTIK for THC

Indications for Use:

1. The ONTRAK TESTSTIK for Amphetamines is an *in vitro* diagnostic test intended for professional use for the qualitative detection of amphetamines in urine at or above a cutoff concentration of 1000 ng/mL.

2. The ONTRAK TESTSTIK for Cocaine is an *in vitro* diagnostic test intended for professional use for the qualitative detection of cocaine metabolite in urine at or above a cutoff concentration of 300 ng/mL.

3. The ONTRAK TESTSTIK for Morphine is an *in vitro* diagnostic test intended for professional use for the qualitative detection of morphine in urine at or above a cutoff concentration of 300 ng/mL

4. The ONTRAK TESTSTIK for PCP is an *in vitro* diagnostic test intended for professional use for the qualitative detection of phencyclidine in urine at or above a cutoff concentration of 25 ng/mL.

5. The ONTRAK TESTSTIK for THC is an *in vitro* diagnostic test intended for professional use for the qualitative detection of cannabinoids in urine at or above a cutoff concentration of 50 ng/mL.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973075

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)