K983388

Roche

NOV 18 1998

510(k) Summary

ONTRAK TESTCUP®-*er*

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

The assigned 510(k) number is: K983388

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 September 24, 1998

Contact: Rita Smith
Senior Regulatory Affairs Associate
Phone: (908) 253-7545
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

Product Name	Classification Name	CFR Number	Regulatory Class
ONTRAK TESTCUP-*er* Barbiturates	Enzyme Immunoassay, Barbiturates	862.3150	Class II
ONTRAK TESTCUP-*er* Benzodiazepines	Enzyme Immunoassay, Benzodiazepines	862.3170	Class II

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

Product Name	Predicate Product Name	Date Predicate Cleared	Predicate 510(k) Number
ONTRAK TESTCUP-*er* Barbiturates	Abuscreen ONTRAK for Barbiturates	7/28/88	K881816
ONTRAK TESTCUP-*er* Benzodiazepines	Abuscreen ONTRAK for Benzodiazepines	4/5/91	K910590

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

The ONTRAK TESTCUP-*er* is an *in vitro* diagnostic test intended for professional use for the qualitative detection of drug or drug metabolite in urine. ONTRAK TESTCUP-*er* simultaneously tests for the presence of multiple drugs or drug metabolites. The ONTRAK TESTCUP-*er* profile consists of amphetamines (1000 ng/mL cutoff), cocaine metabolite (300 ng/mL cutoff), barbiturates (200 ng/mL cutoff), benzodiazepines (200 ng/mL), and morphine (300 ng/mL cutoff).

Measurements obtained by this device are used in the diagnosis and treatment of amphetamine, cocaine, barbiturate, benzodiazepine, and morphine use or overdose.

The ONTRAK TESTCUP-*er* is a modified version of the currently marketed ONTRAK TESTCUP. The ONTRAK TESTCUP-*er* test profile consists of amphetamines, cocaine metabolite, barbiturates, benzodiazepines, and morphine whereas the test profile for the ONTRAK TESTCUP consists of amphetamines, cannabinoids, cocaine metabolite, morphine and phencyclidine. Essentially, cannabinoids and phencyclidine have been replaced with barbiturate and benzodiazepine test strips to create what we now refer to as the ONTRAK TESTCUP-*er*.

The ONTRAK TESTCUP was originally cleared on 12/3/94 (K944231) with a three test profile consisting of cannabinoids, cocaine, and morphine. The addition of amphetamines and phencyclidine were cleared under subsequent 510(k) filings on 10/7/96 (K962411) and 12/13/96 (K964355) respectively.

This submission, therefore, contains information specific to the new barbiturate and benzodiazepine test strips contained within the ONTRAK TESTCUP-*er*. The test strips for amphetamines, cocaine metabolite and morphine have not been changed from the previously cleared product. Information and data for these test strips are contained in (K944231) and (K962411).

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

Tables 3 and 4 outline the technological characteristics (methodologies) of the ONTRAK TESTCUP -*er* 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 and 4 demonstrates the results of clinical and nonclinical studies performed using the ONTRAK TESTCUP-*er*. The significant performance characteristics relied upon for a determination of substantial equivalence are summarized in this chart. This information concludes that the performance of this device is essentially equivalent to other legally marketed devices of a similar kind.

ONTRAK TESTCUP Barbiturates Assay

Table 3

	ONTRAK TESTCUP Barbiturates Assay	**Abuscreen ONTRAK for Barbiturates**
Methodology	Competitive microparticle capture inhibition	Competitive latex agglutination inhibition
Measurement	Qualitative	Qualitative
Sample type	urine	urine
Endpoint read	color	agglutination pattern
Cutoff(s)	200 ng/mL	200 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with mouse monoclonal anti-barbiturates 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA immobilized on a membrane	1. Rabbit anti-barbiturate antibody in a buffered solution 2. Reaction buffer 3. Latex-barbiturate conjugate in a buffered solution
Performance Characteristics:		
Precision	>95% confidence at 150% of cutoff	> 99% confidence at 50% and at 200% of cutoff
Accuracy	N = 50 positives 100 % vs. GC/MS	N = 48 positives 100 % vs. GC/MS

ONTRAK TESTCUP Benzodiazepines Assay

Table 4

	ONTRAK TESTCUP Benzodiazepines Assay	**Abuscreen ONTRAK for Benzodiazepines**
Methodology	Competitive microparticle capture inhibition	Competitive latex agglutination inhibition
Measurement	Qualitative	Qualitative
Sample type	urine	urine
Endpoint read	color	agglutination pattern
Cutoff(s)	200 ng/mL	100 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with sheep polyclonal anti-benzodiazepines 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA immobilized on a membrane	1. Sheep anti-benzodiazepine antibody in a buffered solution 2. Reaction buffer 3. Latex-benzodiazepine conjugate in a buffered solution
Performance Characteristics:		
Precision	>95% confidence at 150% of cutoff	> 99% confidence at 50% and at 200% of cutoff
Accuracy	N = 50 positives 100 % vs. GC/MS	N = 67 positives 98.5 % vs. GC/MS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1998

Rita Smith
Senior Regulatory Affairs Associate
Roche Diagnostic Systems, Inc.
1080 U.S. Highway 202
Somerville, NJ 08876-3771

Re: K983388
Trade Name: OnTrak TesTcup-er
Regulatory Class: II
Product Code: DIO, DKZ, DKN, DJG, JXM
Dated: September 24, 1998
Received: September 25, 1998

Dear Ms. Smith:

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) K983388

Device Name: ONTRAK TESTCUP® - *er*

Indications for Use:

The ONTRAK TESTCUP *-er* is an *in vitro* diagnostic test intended for professional use for the qualitative detection of drug or drug metabolite in urine. ONTRAK TESTCUP-*er* simultaneously tests for the presence of multiple drugs or drug metabolites. The ONTRAK TESTCUP - *er* profile consists of amphetamines (1000 ng/mL cutoff), cocaine metabolite (300 ng/mL cutoff), barbiturates (200 ng/mL cutoff), benzodiazepines (200 ng/mL), and morphine (300 ng/mL cutoff).

Measurements obtained by this device are used in the diagnosis and treatment of amphetamine, cocaine, barbiturate, benzodiazepine, and morphine use or overdose.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983388

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

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)