Roche

K983174

510(k) Summary

ONTRAK TESTSTIK Assays for Barbiturates & Benzodiazepines

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 September 9, 1998

Contact: Maria Feijoo
Manager, Regulatory Affairs
Phone: (908) 253-7310
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	Regulatory Class	CFR Classification Number
ONTRAK TESTSTIK for Barbiturates	Barbiturates test system	Class II	862.3150
ONTRAK TESTSTIK for Benzodiazepines	Benzodiazepines test system	Class II	862.3170

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 TESTSTIK for Barbiturates	Abuscreen OnTrak for Barbiturates	7/28/88	K881816/A
ONTRAK TESTSTIK for Benzodiazepines	Abuscreen OnTrak for Benzodiazepines	4/05/91	K910590

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

The ONTRAK TESTSTIK Assays for Barbiturates and Benzodiazepines are *in vitro* diagnostic tests intended for professional use for the qualitative detection of drug in urine at or above a cutoff of 200 ng/mL.

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 3-4 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 3-4 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 Barbiturates

	ONTRAK TESTSTIK for Barbiturates	**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 antibody 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% cutoff	> 99% confidence at 200% of cutoff

Accuracy: Positive Samples		TesTstik	ONTRAK	GC/MS	GC/MS
	+	50	50	50	48
	-	0	0	0	0

Table 4 - ONTRAK TESTSTIK for Benzodiazepines

	ONTRAK TESTSTIK for Benzodiazepines	**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	200 ng/mL
Reagent (active ingredients)	1. Blue dyed microparticles coated with sheep polyclonal anti-benzodiazepine analogue 2. Drug conjugates immobilized on a membrane 3. Mouse monoclonal anti-BSA antibody immobilized on a membrane	1. Mouse monoclonal 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% cutoff	> 99% confidence at 200% of cutoff

Accuracy: Positive Samples		TESTSTIK	ONTRAK	GC/MS	GC/MS
	+	50	50	50	66
	-	0	0	0	1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1998

Maria Feijoo
Manager, Regulatory Affairs
Roche Diagnostic System, Inc.
1080 U.S. Highway 202
Somerville, NJ 08876-3771

Re: K983174
Trade Name: OnTrak TesTstik for Barbiturates and
OnTrak TesTstik for Benzodiazepines
Regulatory Class: II, II
Product Code: DIS, JXM
Dated: September 9, 1998
Received: September 10, 1998

Dear Ms. Feijoo:

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) K 983174

Device Name: ONTRAK TESTSTIK FOR BARBITURATES
ONTRAK TESTSTIK FOR BENZODIAZEPINES

Indications for Use:

1. The ONTRAK TESTSTIK for Barbiturates is an *in vitro* diagnostic test intended for professional use for the qualitative detection of barbiturates in urine at or above a cutoff concentration of 200 ng/mL.

   Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose.

2. The ONTRAK TESTSTIK for Benzodiazepines is an *in vitro* diagnostic test intended for professional use for the qualitative detection of benzodiazepines in urine at or above a cutoff concentration of 200 ng/mL.

   Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine use or overdose.

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

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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 983174