APR 24 1998

K974840

510(k) Summary

Abuscreen OnLine II for Opiates 300/2000 Reagent
Abuscreen OnLine Opiates Calibration Pack
Abuscreen OnLine Opiates Control Pack

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: K974840

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 December 23, 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	Product Code	Regulation Number
Abuscreen OnLine II for Opiates 300/2000 Reagent	Opiate test system	DJG	862.3650
Abuscreen OnLine Opiates Calibration Pack	Clinical toxicology calibrator	DLJ	862.3200
Abuscreen OnLine Opiates Control Pack	Clinical toxicology control material	DIF	862.3280

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	K number	Date of substantial equivalence
Abuscreen OnLine II for Opiates 300/2000 Reagent	Abuscreen OnLine for Opiates	K951319	6/2/95
Abuscreen OnLine Opiates Calibration Pack	Abuscreen ONLINE MIL Cal Pack	K935550	1/3/94
Abuscreen OnLine Opiates Control Pack	Abuscreen OnLine Controls	K962280	8/16/96

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

Abuscreen OnLine II for Opiates 300/2000 Reagent:

The Abuscreen OnLine II for Opiates 300/2000 Reagent is an in vitro diagnostic test for the qualitative (at 300 and 2000 ng/mL cutoff) and semi-quantitative (at 2000 ng/mL cutoff) detection of morphine and its metabolites in human urine.

Abuscreen OnLine Opiates Calibration Pack:

The Abuscreen ONLINE Opiates Calibration Pack is an *in vitro* diagnostic device designed for the calibration of the Roche reagent assays for opiates.

Abuscreen ONLINE Opiates Control Pack:

The Roche Abuscreen ONLINE Opiates Control Pack is an assayed quality control sample for use with the Roche assays for opiates.

The intended use, clinical utility and methodology of each device is further described in the package inserts, contained in the test specific sections of this submission.

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

Tables 3-5 outline the technological characteristics (methodologies) of each device 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 3-5 demonstrate the results of clinical and nonclinical studies performed using the Abuscreen OnLine II for Opiates 300/2000 Reagent, Abuscreen OnLine Opiates Calibration Pack and the Abuscreen ONLINE Opiates Control Pack, respectively. The significant performance characteristics relied upon for a determination of substantial equivalence are summarized in these charts. This information concludes that the performance of these devices are essentially equivalent to other legally marketed devices of a similar kind.

Table 3 - Abuscreen OnLine II for Opiates 300/2000 Reagent

	Abuscreen OnLine II Opiates Reagent	**Abuscreen OnLine Opiates Reagent**
Methodology	Kinetic interaction of microparticles in a solution	Kinetic interaction of microparticles in a solution
Sample type	urine	urine
Calibrator	For 300ng/mL cutoff: Abuscreen OnLine Calibrator Level 3 For 2000 ng/mL cutoff: Abuscreen OnLine Opiates Calibration Pack	Abuscreen OnLine Calibration Pack Abuscreen ONLINE MiL Calibration Pack
Cutoff	Qualitative: 300 and 2000 ng/mL Semi-quantitative: 2000 ng/mL	Semi-quantitative: 2000 ng/mL
Reagent (active ingredients)	1. Ab/Microparticle reagent: Microparticles attached with opiate monoclonal antibody (mouse)in buffer 2. Conjugate reagent: Opiate conjugated derivative in buffer	1. Ab reagent: Opiate monoclonal antibody in buffer 2. Microparticle reagent: Conjugated opiate derivative microparticles in buffer 3. Diluent
Performance Characteristics: With the 300 ng/mL qualitative application		
Assay range	Up to 2000 ng/mL	Up to 600 ng/mL
Precision: Negative reading Positive reading	 > 95% confidence at 80% cutoff > 95% confidence at 120% cutoff	 >95% confidence at 80% cutoff > 95% confidence at 120% cutoff
Accuracy (% Agreement)	N = 40 100 % vs. GC/MS	N = 49 100 % vs. GC/MS
Sensitivity (Analytical)	< 12 ng/mL	< 5.0 ng/mL

Table 3 - (Cont.')

Performance Characteristics: With the 2000 ng/mL quantitative application		
Assay range	Up to 8000 ng/mL	Up to 4000 ng/mL
Precision (Within-run)	2.2 % at 1000 ng/mL 3.3 % at 1600 ng/mL 2.8 % at2000 ng/mL 3.8 % at 2400 ng/mL 4.2 % at 4000 ng/mL	1.7 % at 246 ng/mL 1.7 % at 297 ng/mL 0.7 % at 359 ng/mL
Accuracy (% Agreement)	N = 42 100 % vs. GC/MS	N = 49 100 % vs. GC/MS
Sensitivity (Analytical)	< 12 ng/mL	< 5.0 ng/mL

Table 4 - Abuscreen OnLine Opiates Calibration Pack

	Abuscreen ONLINE Opiates Calibration Pack	**Current Abuscreen ONLINE MiL Cal Pack**
Matrix	human urine	human urine
Constituents	morphine HCL	morphine sulfate
Calibrator Values: ng/mL	0 600 1000 2000 4000 8000	0 1000 2000 4000

Table 5 - Abuscreen OnLine Opiates Control Pack

	Abuscreen ONLINE Opiates Control Pack		Abuscreen ONLINE Controls	
	Negative	Positive	Negative	Positive
Matrix	human urine	human urine	human urine	human urine
Drugs:	ng/mL	ng/mL	ng/mL	ng/mL
Amphetamines			500	1500
Barbiturates			100	300
Benzodiazepines			50	150
Cannabinoids			20	75
Cocaine			150	450
Methadone			150	450
Methaqualone			150	450
Opiates (Morphine)	1000	3000	150	450
PCP			12.5	38
Propoxyphene			150	450

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 24 1998

James W. Haynes
Regulatory Affairs Associate
Roche Diagnostics Systems, Inc.
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K974840
Abuscreen OnLine II for Opiates 300/2000 Reagent,
Calibration Pack and Control Pack
Regulatory Class: II
Product Code: DJG, DJJ, DLR
Dated: April 3, 1998
Received: April 6, 1998

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 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 (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) K974840

Device Name: Abuscreen OnLine II for Opiates 300/2000
Abuscreen OnLine Opiates Calibration Pack
Abuscreen OnLine Opiates Control Pack

Indications for Use:

The Abuscreen OnLine II for Opiates 300/2000 Reagent is an in vitro diagnostic test for the qualitative (at 300 and 2000 ng/mL cutoff) and semi-quantitative (at 2000 ng/mL cutoff) detection of morphine and its metabolites in human urine.

The Abuscreen ONLINE Opiates Calibration Pack is an *in vitro* diagnostic device designed for the calibration of the Roche reagent assays for opiates.

The Roche Abuscreen ONLINE Opiates Control Pack is an assayed quality control sample for use with the Roche assays for opiates.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of [illegible]
510(k) Number K974840

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)