

K981584



MAY 28 1998

Roche Diagnostics

### 510(k) Summary

#### Abuscreen® OnLine for Cannabinoids (100 Test Kit)

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: K 981584

#### I. Identification of 510(k) Sponsor

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

510(k) Submission dated: April 30, 1998

contact: Rita Smith  
Senior Regulatory Affairs Associate  
Phone: 908-253-7545  
Fax: 908-253-7547  
E-mail: rita.smith@roche.com

#### II. Device Name

Proprietary Name	Classification Name	Product Code
Abuscreen® OnLine for Cannabinoids (1000 Test Kit)	Enzyme Immunoassay, Cannabinoids	LDJ

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

<b>Product Name (modified)</b>	<b>Predicate Product Name</b>	<b>K Number</b>	<b>Date of SE</b>
Abuscreen® OnLine for Cannabinoids (1000 Test Kit)	Abuscreen® OnLine for Cannabinoids (100 Test Kit)	K913414	9/25/91

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

The Abuscreen ONLINE for Cannabinoids (100 Test Kit) is an *in vitro* diagnostic test for the qualitative and semi-quantitative detection of cannabinoids in human urine at 50 and 100 ng/mL cutoffs and the qualitative detection at 20 ng/mL cutoff.. Semi-Quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

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

This product has been modified to include an additional cutoff of 20 ng/mL for detecting cannabinoids in human urine. This cutoff is in addition to the two cutoffs of 50 and 100 ng/mL which are supported in the previously cleared product.

Although the NIDA recommended cutoff for Cannabinoids is 50 ng/mL, this lower cutoff is beneficial to a user who is interested in determining the presence of cannabinoids at a lower level.

The Intended Use statement has also been revised to include an indication for the use of semi-quantitative test results. Previously, the indication for semi-quantitative test results was stated in the "Results" section of the package insert but not in the "Intended Use" section. There is no change in the way results are printed or the utility of the semi-quantitative results. Semi-quantitative values are still only indicated to follow trends in quality control data and to determine dilutions for GC/MS but not to be used in evaluating an individual's test results.

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

The following table summarizes the significant performance characteristics relied on for a determination of substantial equivalence. This information concludes that the performance of these devices are essentially equivalent.

		<b>Modified Product:</b> Abuscreen ONLINE for Cannabinoids (100 Test Kit)				<b>Previously Cleared: (K913414)</b> Abuscreen ONLINE for Cannabinoids (100 Test Kit)			
<b>Performance Characteristics:</b>									
<b>Precision Qualitative:</b>									
20 ng/mL Cutoff	>95% negative at 10 ng/mL >95% positive at 30 ng/mL								
50 ng/mL Cutoff	>95% negative at 40 ng/mL >95% positive at 60 ng/mL				>95% negative at 40 ng/mL >95% positive at 60 ng/mL >95% positive at 80 ng/mL >95% positive at 120 ng/mL				
100 ng/mL Cutoff	>95% negative at 80 ng/mL >95% positive at 120 ng/mL								
<b>Precision Quantitative:</b>									
	<b>Within Run</b>			<b>Day-to-Day</b>			<b>Within Run</b>	<b>Day-to-Day</b>	
<b>20 cutoff:</b>									
Conc. (ng/mL)	10	30		10	30				
Mean (OD)	598	1740		509	1582				
CV %	17	4		19	11				
<b>50 cutoff:</b>	40	50	60	40	50	60	50	50	
Conc. (ng/mL)	41.5	52.5	61.7	40.2	52.0	67.4	49	49	
Mean (ng/mL)	6	7	4	10	11	13	8.4	10.4	
CV %									
<b>100 cutoff:</b>	80	100	120	80	100	120	100	100	
Conc. (ng/mL)	87.2	100.6	137.7	83.9	100.5	133.6	98	98	
Mean (ng/mL)	7	5	7	11	11	8	5.0	8.0	
CV %									
<b>Accuracy</b>									
20 ng/mL Cutoff	N = 55 Confirmed Pos. 54 Pos. 1 Neg.								
50 ng/mL Cutoff	N = 55 Confirmed Pos. 41 Pos. 14 Neg.				N = 247 Confirmed Pos. 245 Pos. 2 Neg.				
100 ng/mL Cutoff	N = 55 Confirmed Pos. 31 Pos. 24 Neg.				N = 206 Confirmed Pos. 187 Pos. 19 Neg.				
<b>Sensitivity (Analytical)</b>	5 ng/mL				5 ng/mL				



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 28 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K981584  
Abuscreen ONLINE for Cannabinoids - 100 Test Kit  
Regulatory Class: II  
Product Code: LDJ  
Dated: April 30, 1998  
Received: May 4, 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 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.

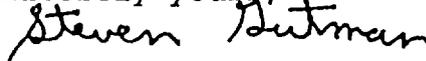
Page 2

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 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) 981584

Device Name: Abuscreen ONLINE for Cannabinoids

Indications for Use:

The Abuscreen ONLINE for Cannabinoids (100 Test Kit) is an *in vitro* diagnostic test for the qualitative and semi-quantitative detection of cannabinoids in human urine at 50 and 100 ng/mL cutoffs and the qualitative detection at 20 ng/mL cutoff. Semi-Quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Alphina A. Montemore*  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number 981584

Prescription Use    
(Per 21 CFR 801.109)

OR

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