DEC 14 1998

K983555

Roche

510(k) Summary

Abuscreen ONLINE® BENZ 200 Calibrators

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: K983555

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 October 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	Product Code	CFR Number and Regulatory Class
Abuscreen ONLINE BENZ 200 Calibrators	Calibrators, Drug Specific	DLJ	862.3200 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	510(k) Number and Date Predicate Cleared
Abuscreen ONLINE BENZ 200 Calibrators	Abuscreen ONLINE Calibration Pack	K951595 9/8/95

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

Abuscreen ONLINE BENZ 200 Calibrators are designed for the calibration of the Roche assays for Benzodiazepines. This clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

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

Tables 3 outlines the characteristics of the Abuscreen ONLINE BENZ 200 Calibrators 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:

No clinical or nonclinical tests were necessary to establish substantial equivalence.

Comparison Summary
Table 3

	Proposed: Abuscreen ONLINE BENZ 200 Calibrators	**Previously Cleared: (K951595)** Abuscreen ONLINE Calibration Pack
Matrix	urine	urine
Intended use	for the calibration of Roche assays for benzodiazepines	for the calibration of Roche assays for amphetamines, barbiturates, benzodiazepines, cocaine metabolite, methadone, opiates and pcp
Levels of Benzodiazepines (ng/mL)	0 100 200 400	0 50 100 200

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 15 1998

Mr. Maria Feijoo
Manager, Regulatory Affairs
Roche Diagnostic Systems, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K983555
Trade Name: Abuscreen ONLINE® BENZ 200 Calibrators
Regulatory Class: II
Product Code: DLJ
Dated: October 9, 1998
Received: October 13, 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.

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/dsma/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) _____

Device Name: Abuscreen ONLINE® BENZ 200 Calibrators

Indications for Use:

Abuscreen ONLINE BENZ 200 Calibrators are designed for the calibration of the Roche assays for Benzodiazepines. This clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

(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 K983555