

K974779

FEB 13 1998

Section III
510(k) Summary

510(k) Summary

Submitter's name/address	Contact Person
Abbott Laboratories	Andrew Johnson
1920 Hurd Drive	Section Manager
M.S. 1-8	Regulatory Affairs
Irving, Texas 75038	(972) 518-7861
	Fax (972) 753-3367
Date of Preparation of this Summary:	December 19, 1997
Device Trade or Proprietary Name:	Abbott ALCYON™ Analyzer
Device Common Name:	Clinical Chemistry Analyzer (with optional ISE Module)
Classification Numbers/Class:	75JJD, Class I 75JGS, Class II 75CEM, Class II 75CGZ, Class II

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

Description:

The ALCYON Analyzer is an automated open system for quantitative analysis of clinical chemistries. The ALCYON Analyzer has an optional Ion-Selective Electrode (ISE) module which measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using indirect potentiometry.

Substantial Equivalence:

Substantial equivalence has been demonstrated between the ALCYON 300 Analyzer, the Synermed™ IR 500 Chemistry Analyzer (K935662), and the Roche® Cobas® Mira Plus (K9720402). The ALCYON 300 Analyzer, the Synermed™ IR 500 Chemistry Analyzer,

and the Roche® Cobas® Mira Plus systems utilize absorbance photometry to perform and output quantitative results for kinetic and endpoint clinical chemistries. For analytes, all three analyzers determine the concentration of unknown samples from a standard curve generated with known analyte concentrations. For enzymes, all three analyzers determine the activity of unknown samples by measuring change in absorbance per unit of time. Substantial equivalence has also been demonstrated between the ALCYON 300i and the IL943™ Automatic Flame Photometer (K823480), the Buchler Instruments Digital Chloridometer (K791312), and the AVL 9181 Electrolyte Analyzer (K972673). All four analyzers are used to analyze for electrolytes. All analyzers are calibrated with known concentration calibrator material. The ALCYON 300i and the AVL 9181 Electrolyte Analyzer both utilize Ion-Selective Electrodes.

Intended Use:

The ALCYON Analyzer is an automated chemistry analyzer for *in vitro* diagnostic use. The analyzer performs quantitative kinetic and endpoint determinations of specific analytes. The ALCYON 300i Analyzer with the ISE Module additionally measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples, using indirect potentiometry.

Performance Characteristics:

A correlation analysis between the ALCYON Analyzer and the Roche® Cobas® Mira Plus yielded the following results:

Representative Method	Correlation Coefficient	Slope (Least-Squares)	Y-axis intercept
Enzymatic Endpoint (Glucose)	0.9891	0.865	-1.698 mg/dL
Non - Enzymatic Endpoint (Total Protein)	0.98	1.02	- 0.035 g/dL
Rate Reaction (GGTP)	0.9989	0.90	-1.467 U/L
Sodium	0.98	1.01	- 4.261 mEq/L
Potassium	0.9981	1.014	- 01.101 mEq/L
Chloride	0.990	0.904	- 10.493 mEq/L

The linearity test yielded the following results:

Representative Method	Linearity
Enzymatic Endpoint (Glucose)	To 700 mg/dL
Non - Enzymatic Endpoint (Total Protein)	To 12 g/dL
Rate Reaction (GGTP)	To 800 U/L
Sodium	To 200 mEq/L
Potassium	To 15.0 mEq/L
Chloride	To 140 mEq/L

The precision of the representative assays was acceptable for both normal and abnormal controls. The total %CV's for both the normal and abnormal controls ranged from 0.7 to 5.6 and 0.5 to 3.1 respectively.

Conclusion:

The data demonstrates that the ALCYON Analyzer and the 300i are substantially equivalent to the Synermed™ IR 500 Chemistry Analyzer, the Roche® Cobas® Mira Plus, the IL943™ Automatic Flame Photometer, the Buchler Instruments Digital Chloridometer, and the AVL 9181 Electrolyte Analyzer.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Andrew Johnson
• Section Manager, Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K974779
ALCYON™ 300 (without ISE Module) and 300i (with ISE
Module) Analyzer
Regulatory Class: I & II
Product Code: JJE, CEM, CGZ, JGS
Dated: December 19, 1997
Received: December 22, 1997

Dear Mr. Johnson:

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 (Pre-market 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 pre-market 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.

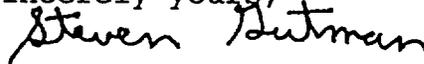
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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): _____

Device Name: ALCYON™ Analyzer

Indications For Use:

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Per 21 CFR, ~~682~~ 2160, the ALCYON Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by performing various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. The analyzer with the optional Ion-Selective Electrode (ISE) Module measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using indirect potentiometry.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 12974779

(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)