510(k) Summary

OCT 5 1999

Submitter's name/address
Abbott Laboratories
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Contact Person
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Regulatory Affairs
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Date of Preparation of this Summary:	September 13, 1999
Device Trade or Proprietary Name:	Abbott ALCYON Analyzer
Device Common Name:	Clinical Chemistry Analyzer (with optional ISE Module)
Classification Numbers/Class:	75JJD, Class 1 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: K993083

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 use of serum specimens and plasma specimens for the quantitative determination of sodium, potassium, and chloride using indirect potentiometry (ISE module) on the ALCYON 300i Analyzer.

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:

Anticoagulant studies were performed using Lithium Heparin, Sodium Heparin, Ammonia Heparin, Sodium Citrate, Potassium-EDTA, plastic tubes and baselined against serum specimen tubes.

Less than ± 10% difference from the serum specimen collection tube baseline was observed for sodium heparin, lithium heparin, ammonium heparin, plastic, and SST collection tubes for the quantitation of sodium, potassium, and chloride.

Sodium Anticoagulant Recovery

Substance	Mean of % Recovery
SST	99.7
NaHep (full draw)	100.7
LiHep	99.6
NH4Hep	99.9
KEDTA	95.0
NaCitrate	138.5
Plastic	99.8
NaHep (1/2 draw)	100.3

Potassium Anticoagulant Recovery

Substance	Mean of % Recovery
SST	99.9
NaHep (full draw)	91.0
LiHep	92.3
NH4Hep	91.2
KEDTA	759.5
NaCitrate	76.7
Plastic	100.8
NaHep (1/2 draw)	92.1

Chloride Anticoagulant Recovery

Substance	Mean of % Recovery
SST	99.7
NaHep (full draw)	100.0
LiHep	99.8
NH4Hep	99.6
KEDTA	99.5
NaCitrate	103.4
Plastic	100.1
NaHep (1/2 draw)	99.9

Conclusion:

The data demonstrates that the use of plasma specimens is an acceptable specimen type for the quantitative determinations of sodium, potassium, and chloride using indirect potentiometry on the ALCYON 300i Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 5 1999

Mr. Mark Littlefield
Section Manager, Regulatory Affairs
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ADD Regulatory Affairs
1920 Hurd Drive
Irving, Texas 75038

Re: K993083
Trade Name: ALCYON™ 300I (with ISE Module) Analyzer
Regulatory Class: II
Product Code: CEM, CGZ, JGS
Dated: September 15, 1999
Received: September 15, 1999

Dear Mr. Littlefield:

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 (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): K993083

Device Name: ALCYON™ Analyzer

Indications For Use:

862.

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 K993083

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)