K980367

APR - 1 1998

Section III

510(k) Summary

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Date of Preparation of this Summary: January 27, 1998

Device Trade or Proprietary Name: AEROSET™ System

Device Common Name: Clinical Chemistry Analyzer

Classification Number/Class: Classification Number 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 following is a brief description of the AEROSET System.

The AEROSET System is a fully automated random access clinical chemistry Analyzer which utilizes spectrophotometry (mono and bichromatic modes of measurement). The AEROSET System has a solid state Ion-Selective Electrode module, trademarked as Integrated Chip Technology™ (ICT), utilizing potentiometry, which can perform electrolyte determinations for sodium, potassium, and chloride. The AEROSET System can run up to 100 different assays simultaneously with a maximum throughput approaching 2000 tests per hour (depending on configuration).

Substantial Equivalence:

Substantial equivalence has been demonstrated between the AEROSET System and the Boehringer Mannheim Diagnostics' Hitachi® 717 Chemistry Analyzer (K872494).

Both systems utilize monochromatic and bichromatic spectrophotometry to perform quantitative kinetic and endpoint clinical chemistries. Both Analyzers perform quantitative analysis of sodium, potassium, and chloride in clinical samples. Both Analyzers have an Ion-Selective Electrode module, the AEROSET is a solid state Ion-Selective Electrode module, trademarked as Integrated Chip Technology™ (ICT).

Intended Use:

The AEROSET System is a fully automated, random access, clinical chemistry Analyzer which utilizes spectrophotometry (monochromatic and bichromatic modes of measurement) for photometric based determinations. The system also has a solid state Ion-Selective Electrode module, trademarked as Integrated Chip Technology™ (ICT), utilizing potentiometry, for electrolyte determinations (sodium, potassium, and chloride).

Performance Characteristics:

A correlation analysis between the AEROSET System and the Boehringer Mannheim Diagnostics' Hitachi 717 Chemistry Analyzer yielded the following results:

Representative Method	Correlation Coefficient	Slope	Y-axis intercept
Total Protein	0.977	0.931	0.105 g/dL
Alkaline Phosphatase	0.99	0.9	3.4 U/L
Creatinine-Serum	0.995	0.924	-0.198 mg/dL
Creatinine-Urine	0.933	0.9743	2.214 mg/dL
Urea Nitrogen	0.996	0.95	-1.114 mg/dL
Sodium-Serum	0.94	0.86	16.14 mmol/L
Sodium-Urine	0.998	0.967	1.227 mmol/L
Potassium-Serum	0.99	1.08	-0.49 mmol/L
Potassium-Urine	0.994	0.856	2.273 mmol/L
Chloride-Serum	0.96	0.93	3.9 mmol/L
Chloride-Urine	0.979	1.02	5.38 mmol/L

The linearity test yielded the following results:

Representative Method	Linearity
Total Protein	To 10.90 g/dL
Alkaline Phosphatase	To 1484.16 U/L
Creatinine-Serum	To 23.82 mg/dL
Creatinine-Urine	To 191.65 mg/dL
Urea Nitrogen	To 123.51 mg/dL
Sodium-Serum	To 182.92 mmol/L
Sodium-Urine	To 398.02 mmol/L
Potassium-Serum	To 8.74 mmol/L
Potassium-Urine	To 400.24 mmol/L
Chloride-Serum	To 148.88 mmol/L
Chloride-Urine	To 411.00 mmol/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 1.0 to 5.3 and 0.7 to 4.0 respectively.

Conclusion:

The data demonstrates that the AEROSET System and the Boehringer Mannheim Diagnostics' Hitachi 717 Chemistry Analyzer are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 1 1998

Andrew Johnson
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Re: K980367
AEROSET™ System
Regulatory Class: II
Product Code: JJE, JGS, CEM, CGZ
Dated: January 27, 1998
Received: January 29, 1998

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 (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): _____

Device Name: AEROSET™ System

Indications For Use:

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Per 21 CFR ~~682~~.2160, the AEROSET System 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, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. The AEROSET System also has a solid state Ion-Selective Electrode module, trademarked as Integrated Chip Technology™ (ICT), utilizing potentiometry, for electrolyte determinations (sodium, potassium, and chloride).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980367

(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)

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