AUG 20 1997

SCIENTIFIC CORPORATION

510(k) Summary

(a) (1) **Submitter's name, address**

AVL Scientific Corporation
33 Mansell Court
Roswell, GA 30076

Contact Person

Randy Byrd
Quality Assurance Manager
(770) 587-4040 x 631

Date of preparation of this summary: 14 July 1997

(2) **Device trade or proprietary name:** AVL 9181 Electrolyte Analyzer

Device common or usual name or classification name

Ion-specific electrolyte analyzer for sodium, potassium and chloride or ionized calcium or lithium.

Product Nomenclature	Classification Number	Class	Panel
ELECTRODE, ION-SPECIFIC, CALCIUM	75 JFP	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, CHLORIDE	75 CGZ	II	CHEMISTRY
FLAME PHOTOMETER, LITHIUM	75 JIH	II	TOXICOLOGY
ELECTRODE, ION-SPECIFIC, POTASSIUM	75 CEM	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, SODIUM	75 JGS	II	CHEMISTRY

(3) **Substantial Equivalence**

The AVL 9181 is an improved design of our existing 9180 Electrolyte Analyzer [K961458] with the addition of an Autosampler to allow automatic sampling of up to 18 sample cups. The 9181 is exactly equivalent to the AVL 9180 with the exception of this single, additional feature. Additionally, for Sodium, Potassium and Lithium the AVL 9181 is substantially equivalent to the I.L. Model 943 Flame Emission Photometer and for Chloride, to the Labconco Digital Chloridometer. The Autosampler used as accessory to the 9181 is the same as already marketed by AVL with the 988-4 Electrolyte Analyzer [K943702] and other 98X version instruments also marketed by AVL.

(4) **Description of the new device**

The existing 9180 Electrolyte analyzer was designed for the eventual addition of this automated sampling feature. The electronics necessary to the control the automatic needle mechanism and sampler were already incorporated in existing circuitry. The 9180 cabinet was initially designed to receive the AVL 988-4 needle mechanism and sampler, so further modification to the 9180 is minimal. Because the 9181 Electrolyte Analyzer is composed of hardware modules from existing devices (9180 and 988-4) minimum risk was taken in terms of function or reliability.

The manual needle mechanism of the 9180 was replaced with the automated needle mechanism from the AVL 988-4. The electronic circuitry to control the needle mechanism are incorporated into the 9180 display board. The sampler is taken from the 988-4 without modification except that the connector is changed to a smaller type. The 9180 main board already incorporated the controller for the sampler.

The 9180 software was modified to add the automatic sampling feature. Calibration and measurement sequences are taken without alteration from the 9180 (sample volume, timing and algorithms). Once the sample probe is positioned in the sample cup, aspiration, measurement, wash and recalibration sequences are identical to the 9180. This not only eliminates any effects to the measurement between automated and manual sampling, but ensures good correlation of measurement to the predicate devices: 9180 and 988-4.

The AVL 9181 Electrolyte Analyzer is a microprocessor-based instrument using ion-selective electrodes for the measurement of sodium, potassium, chloride, ionized calcium and lithium. The user is able to select any one of the measurement modes: whole blood, serum, urine, standard, QC material, acetate or bicarbonate dialysate, depending on the sample type to be analyzed. The analyzer automatically processes the sample through the necessary steps, then prints and displays the results.

In the blood, serum and QC measuring modes, the results for sodium and potassium are reported by default as flame photometry equivalent; chloride, ionized calcium and lithium are reported as ISE direct potentiometric values. The urine mode allows for the measurement of prediluted urine samples for sodium, potassium and chloride. The acetate, bicarbonate and standard modes allow for the measurement of aqueous standards and dialysate solutions and reports as ISE direct potentiometric values.

(5) Intended use of the device.

The AVL 9181 Electrolyte Analyzer is intended to be used for the measurement of sodium, potassium, chloride, ionized calcium and lithium in whole blood, serum or plasma, urine, dialysate solutions, or QC materials as appropriate by minimally trained personnel qualified to perform and to report these values in a clinical laboratory setting. These analytes are commonly used in the diagnosis and management of patients with a broad range of renal, metabolic and cardiovascular disorders and, as such, have come to be among those which are considered by the American Association of Clinical Chemistry to have the potential of being life threatening if left uncontrolled.

(6) Technological characteristics of the device.

Principles of Measurement

The principles of measurement used in the AVL 9181 Electrolyte Analyzer are identical to those principles existing in the the electrolyte analyzers to which substantial equivalence is claimed in paragraph (a)(3) above.

Calibration

The AVL 9181 contains software which permits operation in one of six parameter configurations: $Na^+/K^+/Ca^{++}$, $Na^+/K^+/Cl^-$, $Na^+/K^+/Li^+$, Na^+/K^+, Na^+/Li^+ or Li^+. A 2-point calibration is performed automatically every 4 hours in READY mode, and a 1-point calibration is performed automatically with each measurement.

Technical Specifications

Measured Values

Parameter	Range	Display Resolution	units
whole blood, serum, plasma, dialysate and aqueous solutions			
Sodium	40 - 205	0.1	mmol/L
Potassium	1.5 - 15	0.1 or 0.01	mmol/L
Chloride	50 - 200	0 or 0.1	mmol/L
ionized Calcium	0.2 - 5.0	0.01 or 0.001	mmol/L
Lithium	0.1 - 6.0	0.01 or 0.001	mmol/L
urine			
Sodium	1-300	0	mmol/L
Potassium	4.5 - 120 (60 - 120 with additional dilution)	0.1	mmol/L
Chloride	1 - 300	0	mmol/L

Operating Conditions

- Minimum Sample Size: ..... 95 µL
- Sample Type: ..... heparinized whole blood, serum, plasma, urine aqueous standards and acetate or bicarbonate dialysate solutions
- Sample Application: ..... syringe, capillary or AVL Microsampler, collection tube or sample cup
- Sample Input ..... automatic aspiration
- Ambient Temperature: ..... +15 - +32 °C (59 - 90 °F)
- Relative Humidity: ..... 5% to 95% (non-condensing)
- Type of Measurement: ..... direct potentiometry

Data Management

- Printout ..... Built-in thermal printer
- Interface ..... RS 232 C with selectable baud rate
- Format ..... 8 bits, no parity, 1 stop bit, ASCII or ASTM (bi-directional)

Electrical Supply

- Voltage ..... 100 - 240 VAC (50-60 Hz)
- Power Consumption ..... 1.4 VA max, 375 max.

Dimensions and Weight

- Height x width x depth..... 13.2 x 12.4 x 12.0 inches (33.5 x 31.5 x 29.5 cm)
- Weight..... 13 lb. (6 kg)

Classifications

- Safety category I
- Device type..... B (according to ÖVE-MG/EN 60601-1, IEC 601-1)
- Mode of operation ..... continuous operation
- Protection classification ..... IP 20
- Explosion protection..... the device is not designed for operation in explosive environments
- Approvals ..... CSA, IEC 1010 (TÜV/GS), CE

(b) (1) Summary of nonclinical tests submitted with the premarket notification for the device.

Precision

Typical Within-Run (Swr) Between-Day (Sdd) and Total (ST) Precision is determined from 2 runs per day with 2 replicates per run for 20 days on two model AVL 9181 analyzers in each of its three main configurations using samples of each of the specimen types suitable for measurement on the 9181. Tests were performed in manual measurement mode (some solutions) and in automated measurement (all solutions) to demonstrate no significant difference in performance exists between the 9181 in automated and manual measurement modes; and between the 9181 and its predecessor, the AVL 9180.

Linearity in N.I.S.T. Standard Reference Material

Evaluation of linearity of Sodium, Potassium and Lithium was made in accordance to recommendations by NCCLS[1] using N.I.S.T. SRM 956a Electrolyte in Human Serum:

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x
Sodium	1.0134	-2.5307	0.99988	0.2709
Potassium	1.0133	-0.0230	0.99996	0.0166
Lithium	0.9717	0.0482	0.99998	0.0067

Linearity in Serum

Linearity in serum was evaluated between manual and automated measurement modes. All samples were analyzed in pairs on each of two of AVL 9181 instruments in each configuration: Na/K/Cl, Na/K/iCa and Na/K/Li. and in pairs on each of several instrument types for comparison to various methods, and measurement in

[1] NCCLS. Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard. NCCLS Document C29-A. NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania 19085, 1995.

both manual and automated modes of operation were compared. Linearity to measurement in serum compared to predicate methods evaluated is equivalent, and there is no significant difference in measurement results obtained in either mode of measurement ($p < 0.05$).

Linearity in Urine

Linearity in urine was evaluated with the analysis of random patient urine specimens on two, AVL 9810 Electrolyte Analyzers in the Na/K/Cl configuration and, in duplicate on two AVL 983 Na/K/Cl Electrolyte Analyzers for sodium, potassium and chloride; on a IL 943 Flame Photometer for sodium and potassium; and on a Labconco Digital Chloridometer for chloride. No significant difference ($p < 0.05$) was found between any of the methods evaluated, or between manual and automatic modes of operation.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

Four field tests were conducted to demonstrate the correlation of the AVL 9181 to legally marketed predicate devices in a clinical setting, operated by personnel trained to perform and report these analyses. Specimens analyzed in these tests were remnant from patient specimens of both whole blood and serum collected for routing analysis on existing instrumentation.

In all evaluations, there was no difference in mean values ($P<0.05$) obtained on measurement by the AVL 9181 and the predicate device in either manual or automated measurement mode.

(b) (3) Conclusions drawn from the clinical and nonclinical trials.

Analysis of the comparative measurement presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and nonclinical trials demonstrates that the 9181, with the additional feature allowing the automated analysis of up to 18 samples on a sample wheel is safe and effective. There is no significant difference in the measurement values obtained on whole blood, serum or urine with the AVL 9181 in either automated or manual mode, and those of the predicate devices to which it was compared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Randy Byrd
Quality Assurance Manager
AVL Scientific Corporation
33 Mansell Court
Roswell, Georgia 30076

AUG 20 1997

Re: K972673
Trade Name: AVL 9181 Electrolyte Analyzer
Regulatory Class: II Product Code: CEM
II JFP
II CGZ
II JGS
II JIH
Dated: July 15, 1997
Received: July 16, 1997

Dear Mr. Byrd:

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 requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

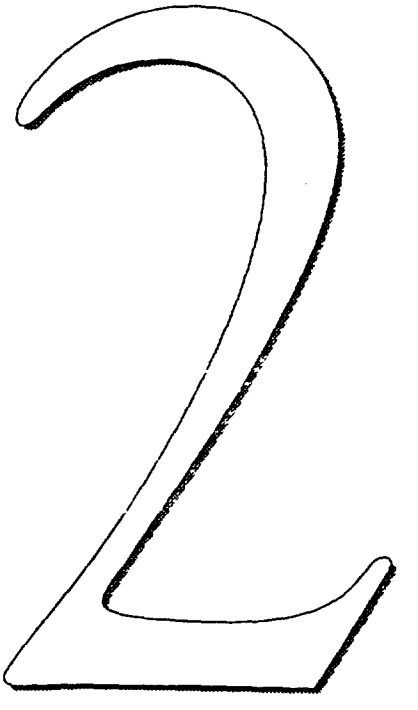
Sincerely yours,

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

Indications for Use



510(k) Number (if known):_____

Device Name: AVL 9181 Electrolyte Analyzer

The AVL 9181 Electrolyte Analyzer is intended to be used for the measurement of sodium, potassium, chloride, ionized calcium and lithium in whole blood, serum or plasma, urine, dialysate solutions, or QC materials as appropriate by minimally trained personnel qualified to perform and to report these values in a clinical laboratory setting.

Indications for Use[1,2]

Sodium

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, hyponatremia, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adreocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, hypernatremia, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the

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[1] Tietz, Norbert W., Ed., Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p.436.

[2] Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1994) pp.1354-1360,2180-2206.

adrenal gland or other diseases involving electrolyte imbalance.ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic; as the result of obstructive or restrictive respiratory diseases.

Potassium

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, hyperkalemia, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K+/H+ exchange and hemolysis of the blood. Low potassium levels, hypokalemia, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea and hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Chloride

Chloride is an anion that exists predominantly in extracellular spaces. It maintains cellular integrity through its influence on osmotic pressure. It is also significant in monitoring acid-base balance and water balance. In metabolic acidosis, there is a reciprocal rise in chloride concentration when the bicarbonate concentration drops.

Decreased levels are found in severe vomiting, severe diarrhea, ulcerative colitis, pyloric obstruction, severe burns, heat exhaustion, diabetic acidosis, Addison's disease, fever and acute infections such as pneumonia. Increased levels are found in dehydration, Cushing's syndrome, hyperventilation, eclampsia, anemia, cardiac decompensation.

Ionized Calcium

Calcium in blood is distributed as free calcium ions (50 %), bound to protein, mostly albumin (40 %) and 10 % bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The

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AVL 9181 Analyzer measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, hypercalcemia, may be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Patients with renal disease caused by glomular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method for accurately monitoring calcium status in renal disease.[3]

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, inadequate calcium intake, vitamin D monitoring, dialysis patients, cancer, pancreatitis, effect of diuretics, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

Lithium

Lithium is a monovalent alkali metal which is usually absent in the human body. It is used in the treatment of manic depression psychosis. The drug has proven highly effective in its intended use but some clinically significant complications have been associated with its use. Lithium binding to the plasma proteins is less than 10% and its half life is 7 - 35 hrs. It is mainly eliminated from the body by urine (95%).
Lithium has a very narrow therapeutic range. Initial dosing is aimed at between 0.80 to 1.20 mmol/L and the long-term maintenance level is 0.60 to 0.80 mmol/L. The concentration of lithium in serum during therapy is closely monitored, because lithium is acutely toxic with concentrations that are slightly higher than the above therapeutic range.

Urine Electrolytes

The electrolytes present in the human body and also ingested daily from food are excreted from the body in a natural circulation via the renal system, into the urine. Measurement of electrolytes in excreted urine gives important information about the efficiency of the kidneys and other

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[3] Burritt MF, Pierides AM, Offord KP: Comparative studies of total and ionized serum calcium values in normal subjects and in patients with renal disorders. Mayo Clinic Proc. 55:606, 1980.

(K)

pathological situations. Urine examinations can be made on a random urine sample or for a quantitative determination on a 24 hour collected urine sample. The quantity of electrolytes excreted per day can be determined by multiplying the measured concentration (mmol/L) with the total quantity of urine excreted in one day.

Dialysate Electrolytes

In the dialyzer arterial blood and suitable dialysate liquids are led to a dialysis membrane in opposite directions. The structure of the membrane is such that it prevents the diffusion of proteins and red blood cells through the membrane. Since the composition of the blood and the dialysate are different, a gradient will be formed at the membrane and thus smaller molecules are activated to diffuse through the membrane. This method is effectively used to remove substances like urea, uric acid which are unable to excrete from the blood because of renal insufficiency.

When the concentration of the electrolytes between the blood and dialysate liquid deviates significantly, the electrolytes diffuse in the direction towards the lower concentration (i.e. from blood into the dialysis liquid or vice versa). Analysis of electrolytes in dialysis is of immense clinical significance and provides useful information to the clinician. The use of ISE's in dialysis are:

- To control the patient's electrolyte balance before, during and after the dialysis for fast recognition of deviations and also for making early corrections.
- To control the electrolyte concentrations in the dialysis liquid. Normally they are prepared by mixing appropriate concentrations of the substances with a defined quantity of distilled water.

N Moore for J Montgomery
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____

(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)

POC/POL

(Optional Format 1-2-96)