APR 26 1996

K961161

510(k) Summary

SCIENTIFIC CORPORATION

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

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Date of preparation of this summary: 19 March 1996

(2) Device trade or proprietary name: AVL OPTI 1 pH/Blood Gas Analyzer

Device common or usual name or classification name

pH / Blood Gas Analyzer

Product Nomenclature	Classification Number	Class	Panel
BLOOD GASES / PH	75 CHL	II	CHEMISTRY

(3) Substantial Equivalence

Under 510(k) notification number K944089, AVL currently markets the AVL OPTI 1 pH/Blood Gas Analyzer.

Additionally, as in the former 510(k) submission, the AVL OPTI 1 is substantially equivalent to the AVL Model 995 pH / Blood Gas Analyzer [K895317] and AVL COMPACT 2 pH / Blood Gas Analyzer [K942616].

(4) Description of the new device

The AVL OPTI 1 is a microprocessor-based instrument using optical fluorescence for the measurement of pH, PCO_2 and PO_2 in samples of whole blood. A disposable, single-use cassette containing three optical fluorescence sensors is packaged in a sealed, foil pouch which bears a bar coded label with calibration and identification information. Immediately prior to use, the bar coded calibration information is read into the instrument and the cassette positioned in the instrument for calibration verification prior to measurement using a liquid buffer contained within the cassette, and a precision calibration gas contained in a cylinder inside the OPTI 1.

In order to provide our customers with an additional level of security in the quality control of results obtained with the OPTI 1, AVL has modified the operation of the OPTI 1 to allow the measurement of a traditional, ampouled, aqueous quality control product *prior* to any measurement of a patient's blood specimen in the same cassette. In this way, the customer is provided the advantage to develop a quality control program for the OPTI 1 from a selection or combination of traditional and non-traditional methods which fulfills the real and perceived requirements under CLIA '88 and various laboratory accreditation organizations.

(5) Intended use of the device.

The AVL OPTI 1 pH / Blood Gas Analyzer is intended to be used for the measurement of pH, PCO_2 and PO_2 in samples of whole blood in either a traditional blood gas or clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

(6) Technological characteristics of the device.

The OPTI 1 pH Blood Gas Analyzer uses fluorescence optode technology similar to that used in commercially available products since late 1983 and is unchanged in principle of operation from the originally submitted 510(k) for this device.

Calibration

A disposable, single-use cassette contains all the elements needed for calibration, QC sample measurement, patient sample measurement and waste containment. After reading the calibration information specific to a cassette into the instrument by 'swiping' the cassette packaged through a convenient bar code reader, the cassette is placed into the measurement chamber. The analyzer warms the cassette to 37.0 ± 0.1 °C, and performs a calibration verification on the sensors for pH, pCO_2 and pO_2 by passing a precision calibration gas mixture across the optode sensors. The pH channel is calibrated with precision pH buffer solution contained in the cassette.

Technical Specifications

Measured Values

Parameter	Range	Display Resolution	units
pH	6.9 to 7.7	0.001	pH units
PCO_2	10 to 120	0.1	mmHg
PO_2	20 to 500	0.1	mmHg
Barometric Pressure	300 to 800	0.1	mmHg

Operating Conditions

- Minimum Sample Size: ..... 80 µL
- Sample Type: ..... heparinized whole blood
- Sample Application: ..... syringe, capillary or AVL Microsampler
- Sample Input ..... automatic aspiration
- Ambient Temperature: ..... 15 - 32 °C (59 - 90 °F)
- Relative Humidity: ..... 5% to 95% (non-condensing)
- Type of Measurement: ..... fluorescence

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 (max.) ..... 110 VA

Dimensions and Weight

- Height x width x depth .... 4.87 x 14.25 x 9.75 inches (12.5 x 36.2 x 24.8 cm)
- Weight ..... 10 lb. (4.53 kg)

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

In order to assess the effects of carry-over or memory between the measurement of OPTI-trol and a whole blood patient specimen, tonometered whole blood specimens were analyzed on a group of four (4) OPTI 1 instruments in both modes of operation: OPTI-trol and Patient. Each measurement of OPTI-trol was followed by a blood measurement in the same cassette, then a second measurement taken in the same instrument with a second cassette. This protocol was repeated to obtain 3 sets of measurement for each mode of operation for each of 5 levels of gas containing CO_2 and O_2, and then repeated for each of the three levels of OPTI-trol. No significant difference ($P<0.05$) was demonstrated between the measurement of the blood specimens in either of the measurement modes; or between any of the levels of OPTI-trol.

Whole blood samples were analyzed on four (4) OPTI 1 systems and on 1 AVL 995 after being tonometered at 37 °C to various concentrations of CO_2 and O_2 concentrations certified to 0.03% absolute by the manufacturer. The 995 was confirmed to have measurement of N.I.S.T. traceable pH buffer solutions (QUALIDATA, RNA Medical), at 6.841 ± 0.005, 7.100 ± 0.005, 7.383 ± 0.005 and 7.600 ± 0.005 each day prior to measurement of blood specimens.

Parameter	Slope	Y-Intercept	Correlation Coefficient	Sy*x	Range
pH					
OPTI-trol Mode	1.0081	-0.046	0.9994	0.0067	7.0 - 7.6
Patient Mode	0.9905	0.076	0.9997	0.0047	"
Total	0.9993	0.015	0.9996	0.0051	"
PCO_2					
OPTI-trol Mode	0.9954	+0.119	0.9998	0.6822	11-104
Patient Mode	1.0038	-0.084	0.9998	0.6697	"
Total	0.9996	+0.017	0.9998	0.6243	"
PO_2					
OPTI-trol Mode	0.9636	1.1497	0.99996	1.5635	21-515
Patient Mode	0.9704	0.8665	0.99994	1.8235	"
Total	0.9670	1.0081	0.99996	1.5773	"

Model equation for regression statistics is: [results of OPTI 1 Analyzer] = slope(m) [comparative method results] + intercept(b).

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

Three field tests were conducted to demonstrate the correlation of the AVL OPTI 1 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 collected for routing analysis on existing instrumentation. Measurement was accomplished in both modes of operation (OPTI-trol Mode and Patient Mode) on whole blood specimens for pH, PCO_2 and PO_2 in comparison to:

IL Model 1312 pH/Blood Gas Analyzer, AVL 995 pH / Blood Gas Analyzer and AVL OMNI pH / Blood Gas / Electrolyte and tHb Analyzer

In all evaluations, there was no difference in mean values ($P<0.05$) obtained on blood sample measurement performed with our without the prior analysis of OPTI-trol. The table below provides data representative of that collected in these field tests.

Comparative Method:
IL 1312 pH/Blood Gas Analyzer

Parameter	Slope	Y-Intercept	Correlation Coefficient	Sy*x	n	Range
pH						
OPTI-trol Mode	1.0174	-0.1285	0.9869	0.0210	92	6.90 - 7.58
Patient Mode	1.0392	-0.2924	0.9881	0.0181	92	"
Total	1.0304	-0.2266	0.9908	0.0173	101	"
PCO_2						
OPTI-trol Mode	1.0924	-4.1204	0.9951	1.5905	92	23 - 110
Patient Mode	1.0806	-2.9589	0.9930	1.7704	92	"
Total	1.0938	-3.8301	0.9951	1.5302	101	"
PO_2						
OPTI-trol Mode	0.9295	9.0345	0.9850	6.4536	92	30 - 271
Patient Mode	0.9590	4.7543	0.9918	5.1072	92	"
Total	0.9532	6.0512	0.9904	5.3436	101	"

(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 AVL OPTI 1, with the additional feature allowing the analysis of OPTI-trol quality control liquid prior to patient sample analysis, is safe and effective. There is no significant difference in the measurement values obtained on whole blood with the AVL OPTI 1 and those obtained with predicate devices in this study, with or without the analysis of OPTI-trol as a quality control specimen prior to patient sample analysis.