

# 510(k) Summary

JAN 22 1998

SCIENTIFIC CORPORATION

(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:** 8 January 1998

(2) **Device trade or proprietary name:** AVL OPTI-Check Control  
**Device common or usual name or classification name**

Multi Analyte Control Solution

| PRODUCT NOMENCLATURE           | CLASSIFICATION |       |           |
|--------------------------------|----------------|-------|-----------|
|                                | NUMBER         | CLASS | PANEL     |
| MULTI ANALYTE CONTROL SOLUTION | 75 JJY         | I     | CHEMISTRY |

(3) **Substantial Equivalence**

AVL OPTI-check is substantially equivalent in function, safety and efficacy to a number of currently marketed devices known as 'Combi' or 'Multi-Analyte' control solutions, namely:

- Multi-Function Blood Gas Control, Bionostics, Inc., K880447
- Control for Blood Gases, Electrolytes and Glucose, Bionostics, Inc., K911755

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

OPTI-check is a specially formulated aqueous liquid material intended to for use to monitor all analytes measured by the OPTI. It contains a stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similar to erythrocytes, allowing true simulation of the measurement of tHb and SO<sub>2</sub> in exactly the same manner as these analytes are determined in whole blood by the AVL OPTI Critical Care Analyzer. The three control levels contain three different concentrations of microbeads to simulate low, medium, and high hematocrit blood samples. OPTI-check provides a convenient method of performing daily QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program.

While the product is optimized for performance on the AVL OPTI Critical Care Analyzer, it may be used to monitor the measurement of blood gas and electrolyte values in conventional instrumentation. OPTI-check contains clinically relevant quantities of pH, PCO<sub>2</sub>, PO<sub>2</sub>, sodium, potassium, ionized calcium and chloride, and suitable concentrations of microbeads to simulate clinically relevant values of tHb and oxygen saturation.

**(5) Intended use of the device**

AVL OPTI-check assayed control is intended to be used to monitor the measurement of pH,  $PCO_2$ ,  $PO_2$ , sodium, potassium, total hemoglobin content and oxygen saturation in the AVL OPTI Critical Care Analyzer, as well as other devices measuring the same parameters and ionized calcium and chloride.

**(6) Technological characteristics of the device.**

AVL OPTI-check is technologically equivalent to currently marketed products to which substantial equivalence is claimed. It contains a low concentration, stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similar to erythrocytes, allowing true simulation of the measurement of tHb and  $SO_2$  in exactly the same manner as these analytes are determined in whole blood by the AVL OPTI Critical Care Analyzer.

**(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.**

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) precision were determined from two runs per day with 2 replicates per run for 20 days on two AVL OPTI Critical Care Analyzers.

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

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) precision were determined from two runs per day with 2 replicates per run for 20 days on a single AVL OPTI Critical Care Analyzer. Additionally, clinical testing was conducted to demonstrate the correlation of AVL OPTI Critical Care Analyzer to 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.

**(b) (3) Conclusions drawn from the clinical and non-clinical trials.**

All evaluation of measurement imprecision was within manufacturer's stated claims and comparison of measurement between the OPTI Critical Care Analyzer and other instrumentation showed no significant difference ( $P < 0.05$ ) for all analytes evaluated. Acceptable performance on precision evaluation conducted concurrently to acceptable correlation to predicate devices in measurement of pH,  $PCO_2$ ,  $PO_2$ , Na, K, ctHb and  $SO_2$  supports the use of AVL OPTI-check to monitor the measurement of these analytes, and demonstrates it substantially equivalent to other products with similar intended uses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 22 1998

Randy Byrd  
• Quality Assurance Manger  
AVL Scientific Corporation  
33 Mansell Court  
Roswell, Georgia 30076

Re: K974822  
AVL OPTI-check pH Control  
Regulatory Class: I  
Product Code: JJY  
Dated: December 19, 1997  
Received: December 24, 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 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.

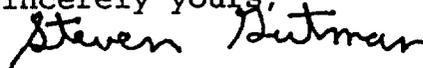
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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: K974822

**Device Name:** AVL OPTI-check Control Solution

AVL OPTI-check assayed control is intended to be used to monitor the measurement of pH,  $PCO_2$ ,  $PO_2$ , sodium, potassium, total hemoglobin content and oxygen saturation in the AVL OPTI Critical Care Analyzer, as well as other devices measuring the same parameters and ionized calcium and chloride.

For *In Vitro* Diagnostic Use

**Indications for Use**

The determination of acid-base status, and concentration of carbon dioxide, oxygen, electrolytes, total hemoglobin and oxygen saturation is an important adjunct to patient monitoring for a variety of clinical conditions described in the labeling for those devices used for these purposes. Since therapeutic regimes are often determined by the results obtained in patient samples, the instruments used for these analyses must meet stringent requirements for accuracy and precision of measurement. It should be the goal of the quality control program in institutions performing these analyses to determine the instrumentation is working properly before the analysis and report of patient specimens, or after any suspicious results have been obtained.

  
974822  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 974822  
\_\_\_\_\_

(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)

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