

K980178  
Feb. 12, 1998

# BIONOSTICS

## 510(k) Summary

(a)(1) Submitter's name, address	Contact Person
Bionostics, Inc	Bruce Williams
2 Craig Road	Ex. Vice President
Acton, MA 01720	978 263 3856 Ex 212

Date of preparation of this summary: 16 January 1998

(2) Device trade name: Oxyhemoglobin CO-Oximeter Control

Device common name or classification name: Multi Analyte Control  
Classification number and Class: 75JJY, Class I

(3) Substantial Equivalence:

Oxyhemoglobin CO-oximeter Control is substantially equivalent in function, safety and efficacy to at least two products currently marketed:

- a. Bionostics 282 CO-Oximeter Control (510(k) clearance K832066A, 6/22/83), and,
- b. Multi-4 CO-Oximeter Control manufactured by Instrumentation Laboratory, Lexington, MA 02173 (510(k) clearance K861901).

Both materials have as their intended use, the quality control of certain analytical instruments.

(4) Description of the new device

Oxyhemoglobin CO-Oximeter Control is prepared by purifying bovine blood to different to different concentrations of hemoglobin. The solution is then treated with oxygen, carbon dioxide and carbon monoxide to provide different defined values for the hemoglobin fractions of oxyhemoglobin, carboxyhemoglobin and methemoglobin. The solution is packaged in sealed glass ampuls to assure the integrity of all control values. The material contains no human based materials.

## **510(k) Summary** (continued)

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

The Oxyhemoglobin CO-Oximeter Control is intended for use to monitor CO-oximetry measurements of hemoglobin and hemoglobin fractions in instruments which measure the optical absorption characteristics of whole blood at specific wavelengths.

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

Oxyhemoglobin CO-Oximeter Control is equivalent in its technology to the currently marketed devices to which substantial equivalence is claimed. The process for purifying the treating the bovine blood makes it possible to have stable hemoglobin species, including oxyhemoglobin.

**(b)**

### **(1, 2) Summary of performance testing submitted with the premarket notification for the device.**

The Oxyhemoglobin CO-Oximeter Control was tested for performance as a quality control material on 8 of CO-oximeter instrument models. The testing has took place in both the Bionostics' lab as well as in clinical laboratories. The test data is summarized in Chart B.

### **(b)(3) Conclusions drawn from the clinical and non-clinical testing**

The testing verification that the Oxyhemoglobin CO-Oximeter Control provides sufficient accuracy and precision in measurements of total hemoglobin and hemoglobin fractions to be suitable for monitoring the performance of CO-oximeters. Also, the test results show suitable of the product for use on different CO-oximeter models, each of which employ slightly differing operating methodology. Finally, the data collected shows the product has substantially equivalent performance to the predicate products which have similar intended uses.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Bruce R. Williams  
Executive Vice President  
BIONOSTICS  
2 Craig Road  
Acton, MA 01720-5405

FEB 12 1998

Re: K980178  
Trade Name: Oxyhemoglobin Control for CO-oximetry  
Regulatory Class: I  
Product Code: JJY 75  
Dated: January 16, 1998  
Received: January 20, 1998

Dear Mr. Williams:

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 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.

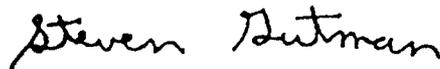
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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

# BIONOSTICS

510(k) Number: K980178 (Not yet assigned)

## INDICATIONS FOR USE

Device Name: Oxyhemoglobin Control for CO-oximetry

Date of Premarket Submission: January 16, 1998

### A. INTENDED USE

The Oxyhemoglobin Control for CO-Oximetry is intended for use to monitor CO-oximetry measurements of hemoglobin and hemoglobin fractions in instruments which measure the optical absorption characteristics of whole blood at specific wavelengths.

To make possible verification of instrument performance at different points for each analyte, the Control has different clinically significant values for total hemoglobin, oxyhemoglobin, carboxyhemoglobin and methemoglobin.

This product is for In Vitro Diagnostic Use only.

### Indications for Use:

The measurement of the concentrations of total hemoglobin, oxyhemoglobin, carboxyhemoglobin, and methemoglobin can serve to monitor tissue oxygenation and therefore the various metabolic factors which effect oxygen transport of blood. Since therapeutic regimes are often determined by the result obtained in patient samples, the instruments used for these analyses must meet clinical requirements for precision and accuracy. The use of control materials are designed to verify test results and assist in identifying instrument calibration or operating problems.

Prescription Use

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Tenaglia for AL Montgomery  
(Division Sign)

Division of

510(k) Number

K980178