

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k053327

B. Purpose for Submission:

Clearance to market quality control material for oxygen saturation meters.

C. Measurand:

The product under submission serves as a control for a device that measures oxygen saturation in whole blood.

D. Type of Test:

Quality Control

E. Applicant:

Bionostics Inc.

F. Proprietary and Established Names:

Oxicom Controls

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660: Quality control material (assayed and unassayed).

2. Classification:

Class I (reserved)

3. Product code:

JJX

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

Please see indications for use.

2. Indication(s) for use:

Oxicom Control is intended to be used to monitor and evaluate the analytical performance of the Waters Oxicom model 2000, 2100 and 3000 oxygen saturation meters for the measurement of oxygen saturation. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The three levels of oxygen saturation provided by the controls allow performance monitoring with the clinically important range. For In Vitro diagnostic Use.

3. Special conditions for use statement(s):

For Prescription Use Only.

4. Special instrument requirements:

Waters Oxicom oxygen saturation meters: models 2000, 2100, 3000.

I. Device Description:

The Oxicom Control is a liquid solution with dyes and polystyrene beads used to mimic the absorbance of whole blood at a range of oxygen saturation levels. The concentration of beads and dyes are designed to simulate the behavior of whole blood at the wavelengths used by Waters Oxicom Systems. These liquid controls can be handled as normal patient samples and can be incorporated into the clinical workflow.

J. Substantial Equivalence Information:

1. Predicate device name(s):

OPTI-Check Quality Control
Oxicom 2100 QC Filters

2. Predicate 510(k) number(s):

K974822: OPTI-Check Quality Control
 K921519: Oxicom 2100 QC Filters

3. Comparison with predicate:

Similarities		
Item	Device	Predicate(K974822)
Intended Use	As a quality control material in the measurement of oxygen saturation	Same
Number of levels	3	Same

Differences		
Item	Device	Predicate(K974822)
Material	Aqueous solution containing suspended styrene beads and dyes	Aqueous solution containing suspended styrene beads.
Supported Platform	Waters Oxicom systems	AVL OPTI
Additional analytes	None	pH, PCO ₂ , PO ₂ , Na,K, Cl, iCa, tHb

K. Standard/Guidance Document Referenced (if applicable):

ISO 14971:2000: Medical devices - Application of risk management to medical devices.

ISO 15223: Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied.

FDA Guidance: “Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use”

Available at:

<http://www.fda.gov/cdrh/ocd/guidance/4444.pdf>

FDA Guidance: “Points to consider guidance document on assayed and unassayed quality control material”.

L. Test Principle:

The product under submission is used to verify the performance of Oxicom analyzers. The control is treated as a typical sample. Processing is done per instrument instructions.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The performance of this control was verified by comparing it to the existing Oxicom 2100 QC Filters used for quality control on the required Waters Oxicom Systems instruments. Samples were run once a day for 30 days. The results are presented in the table below.

		Oxicom Controls		
Oxicom Model		High Control	Mid Control	Low Control
2000	n	30	30	30
	Mean	83.4	72.7	48.7
	SD	0.40	0.69	1.39
	CV%	0.5%	1.0%	2.9%
2100	n	30	30	30
	Mean	86.7	75.9	51.4
	SD	0.30	0.67	1.27
	CV%	0.3%	0.9%	2.5%
3000	n	30	30	30
	Mean	83.0	72.0	47.9
	SD	0.55	0.69	1.03
	CV%	0.7%	1.0%	2.1%

b. *Linearity/assay reportable range:*

Not applicable for a device of this type.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignment is determined based upon replicate assays of representative samples of controls on multiple instruments and lots of measurement kits.

The proposed device will serve as a quality control material for Waters Oxicom oxygen saturation meters. The stability of the device is one of the primary criteria for acceptance.

The company assessed the opened shelf life of the device through real-time studies designed to mimic the behavior of device in the hands of the users. The company evaluated the performance of open but capped material by comparing measurements on this opened material to material that had not been unsealed. Both the opened and unopened material were measured on 5 Oxicom instruments. Measurements were made weekly. All material demonstrated significantly less than a 10% change in behavior, the performance criteria set for the product. The data supplied by the company supports the 2 month opened shelf life claimed by the company.

The company assessed the shelf life of the product through a series of accelerated aging studies. The data supplied by the company supports the 3 year shelf life claimed by the company.

d. Detection limit:

Not applicable for a device of this type.

e. Analytical specificity:

Not applicable for a device of this type.

f. Assay cut-off:

Not applicable for a device of this type.

2. Comparison studies:

a. *Method comparison with predicate device:*

The company demonstrated their equivalence by direct comparison to the existing Oxicom 2100 QC Filters on the required Waters Oxicom Systems instruments.. Measurement comparisons were made across all 3 model lines and on multiple instruments within in each product line. Samples were run once a day for 30 days. The results are presented in the table below.

Oxicom Model	Oxicom Controls			Existing QC Method		
	High Control	Mid Control	Low Control	QC 1	QC 2	QC 3
2000 n	5	5	5	5	5	5
Mean	85.1	72.6	52.3	83.9	91.3	65.4
SD	0.57	0.75	1.71	0.90	2.39	7.02
CV%	0.7%	1.0%	3.3%	1.1%	2.6%	10.7%
2100 n	22	22	22	22	22	22
Mean	84.9	72.4	54.1	77.3	85.7	69.6
SD	0.81	1.05	2.78	10.31	2.74	11.41
CV%	1.0%	1.5%	5.1%	13.3%	3.2%	16.4%
3000 n	14	14	14	14	14	14
Mean	85.1	73.0	54.0	82.1	89.5	61.4
SD	0.70	0.96	2.38	4.77	2.84	8.65
CV%	0.8%	1.3%	4.4%	5.8%	3.2%	14.1%

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable for a device of this type.

b. *Clinical specificity:*

Not applicable for a device of this type.

c. *Other clinical supportive data (when a. and b. are not applicable):*

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Oxygen saturation in blood, expressed as a percentage, can range from 0% - 100%.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.