

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

A. 510(k) Number:

K042750

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for sperm counts

D. Type of Test:

Quantitative

E. Applicant:

Bioscreen, Inc.

F. Proprietary and Established Names:

QC-Bead™

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625, Hematology Quality Control Mixture

2. Classification:

Class II

3. Product code:

NRF, Material, Quality Control, Semen Analysis

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

QC-Beads™ are intended for use as controls in counting sperm manually using a microscope or automatically using computer assisted semen analysis instruments.

2. Indication(s) for use:

QC-Beads™ are intended for use as controls in counting sperm manually using a microscope or automatically using computer assisted semen analysis instruments.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

QC-Beads™ are used in conjunction with single-use cell-counting chambers, the Makler Chamber, hemacytometers or similar cell-counting devices for sperm concentration.

I. Device Description:

QC-Beads™ consists of polystyrene latex beads of 3.7-µm diameter suspended in a solution of glycerol and detergent in water with 0.1% sodium azide added as a preservative. QC-Beads™ is supplied in two levels, one 4.0-ml bottle per level per box. The concentration of beads at each level is in the physiological range concentration of sperm in semen. According to the World Health Organization (WHO), the Lo QC-Beads™ fall in the range around the reference value of sperm concentration which is 20 million or more sperm/ml. The Hi QC-Beads™ fall in the range above the reference range value of sperm concentration.

QC-Beads™ are packaged in 4-ml narrow-mouth bottles composed of high density polyethylene (HDPE) that are manufactured by Nalgene.

J. Substantial Equivalence Information:

1. Predicate device name(s):

QwickCheck-beads™

AQC™ Sperm Count

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

K051600, K041240

3. Comparison with predicate:

Similarities			
Item	Device	Predicate	Predicate
	<i>QC-Beads™</i>	<i>QwickCheck-beads™</i>	<i>AQC™ Sperm Count</i>
Intended Use	Used as quality control for sperm count	Same	Same
Design	Two levels	Same	Same

Differences			
Item	Device	Predicate	Predicate
Materials	Liquid suspension containing latex particles.	Same	Liquid human semen matrix and stabilized human sperm cells.
Storage	Room temperature	Same	2-8°C
Expected value	Hi QC-Beads™ = 34-46 million beads/ml Lo QC-Beads™ = 16-24 million beads/ml	High Level @ 40 million beads/ml Low Level @ 20 million beads/ml	Level One = 0-30 million/ml Level Two = 30-75 million/ml

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

World Health Organization, 1992, 1999. WHO laboratory Manual for the examination of human semen and sperm-cervical mucus interaction, Cambridge University Press.

L. Test Principle:

Not Applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Duplicate aliquots of the Hi and Lo QC Beads were counted 10 times using a Neubauer hemacytometer and a bright-field microscope. The results of the counts were within the expected range with a CV of 9-11%

b. Linearity/assay reportable range:

Not Applicable.

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

Stability: Duplicate bottles of the Hi and Lo QC Beads were stored at room temperature for 14 months and demonstrated a stability of at least one year when stored at room temperature.

Expected Range: Lo QC Beads- 16-24 million beads/ml

Hi QC Beads- 34-46 million beads/ml

d. Detection limit:

Not Applicable.

e. Analytical specificity:

Not Applicable.

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable.

b. Matrix comparison:

Not Applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

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

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The concentration of beads at each level is in the physiological range of concentration of sperm to semen. According to the World Health Organization (WHO), the Lo QC-Beads™ fall in the range around the reference value of sperm concentration which is 20 million or more sperm/ml. The Hi QC-Beads™ fall in the range above the reference value of sperm concentration.

Lo QC-Beads™ = 16-24 million beads/ml

Hi QC-Beads™ = 34-46 million beads/ml

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.