

**510(k) DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K041600

B. Analyte:

Quality control material for automated or manual sperm counts

C. Type of Test:

Quantitative

D. Applicant:

Medical Electronic Systems, (MES), Ltd.

E. Proprietary and Established Names:

QwickCheck-beads™

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1660, Quality Control, Assayed Material
2. Classification:
Class I
3. Product Code:
JJW (Urinalysis Controls)
4. Panel:
Chemistry (81)

G. Intended Use:

1. Indication(s) for use:
QwickCheck-beads is intended for in vitro diagnostic use as sperm concentration quality control material for the SQA-V system (MES Ltd., Israel) in both the automated and manual visualization modes, as well as non-instrumented sperm cell counting chambers such as the hemacytometer (Neubauer type and non-dilutional chamber (Makler type).
2. Special condition for use statement(s):
N/A
3. Special instrument Requirements:
N/A

H. Device Description:

QwickCheck-beads are an aqueous solution of polystyrene latex beads in two known concentrations. Level I: High level has a concentration of @ 40 million beads/mL. Level II: Low level has a concentration of @ 20 million beads/mL. Level II is significant because the 20 million figure represents the WHO reference value of 20

million spermatozoa /mL, indicating fertility or infertility. Level I is significant because the 40 million level represents the WHO reference value of 40 million spermatozoa / ejaculate or more. QwikCheck-beads contain latex beads, glycerol, 0.1% sodium azide as a preservative, detergent and distilled water. These controls are ready to use.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Quantimetrix Urinalysis and Microscopics Control
2. Predicate K number(s):
K925256
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Regulation Number and Definition	21 CFR 862.1660, Multi-analyte controls, all kinds, assayed and unassayed	Same
Chosen Preservative	sodium azide	Same
Differences		
Item	Device	Predicate
Intended Use	QC material for automated and manual determination of sperm concentration. Intended to validate the performance of analysis system.	QC material for automated and manual determination of routine urinary constituents. Intended to validate the performance of the analysis system.
Material Composition	Latex bead suspension in aqueous solution	Prepared from human urine to which stabilized cells, crystals, and other components have been added.
User Requirements	Controls are supplied liquid, ready-to-use, and are stored at room temperature.	Controls are supplied liquid, ready-to-use, and are stored refrigerated and used at room temperature.

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

WHO laboratory manual for the examination of human semen and sperm-cervical mucus interaction, 4th Edition

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

In-house precision studies were conducted. Five lots each of QwikCheck-beads Level I (High) and Level 2 (Low) (total of 10 lots) were tested by five different counting methods, inclusive of the SQA-V in the automated and manual visualization modes, and three manual counting chambers. Testing with the SQA-V in the automated mode consisted of four replicates on each of eight systems, providing 32 results per level, per lot. Testing by manual methods consisted of “runs” of 20 replicates with each lot and level. The testing was performed over several days.

The data demonstrated that the results were within the target ranges a minimum of 90% of the time, with most methodologies achieving the target ranges 95% to 100% of the time. The coefficients of variation (CVs %) among the testing platforms ranged from @ 5% to @ 14% with the lowest CVs for the SQA-V in the automated mode.

b. *Linearity/assay reportable range:*

N/A

c. *Traceability (controls, calibrators, or method):*

N/A

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

2. Comparison studies:a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:a. *Clinical sensitivity:*

N/A

b. *Clinical specificity:*

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:
Level 1: High Level, @ 40 million beads/mL
Level 2: Low Level, @ 20 million beads/mL

M. Conclusion:

Medical Electronic Systems' QuikCheck-beads is substantially equivalent to the Quantimetrix Urinalysis and Microscopics Control.