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

A. 510(k) Number:

K090201

B. Purpose for Submission:

New Device

C. Measurand:

White Blood Cells (WBC), Red Blood Cells (RBC), Non-squamous Epithelial Cells, Crystals

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

UA-Cellular™ for IQ

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625, Hematology Quality Control Mixture

2. Classification:

   Class II

3. Product code:

   JPK, Mixture Hematology Quality Control

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

UA-Cellular™ for IQ is an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters.

2. Indication(s) for use:

UA-Cellular™ for IQ is an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

For use on the IRIS IQ 200 analyzer.

I. Device Description:

UA-Cellular™ for IQ is a urinalysis control which contains stabilized human red and white blood cells and other inert particles in a preservative medium. UA-Cellular™ for IQ is a urine control for the IRIS IQ 200 analyzer. The product is packaged in plastic bottles containing 120ml. The closures are propropylene screw caps with polyethylene liners. There are two different levels; level 1 and level 2. The bottles are packaged in a box with the package insert/ assay sheet. The product is stored a 2-10° C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Cell-Chex Auto

2. Predicate K number(s):

K053362

3. Comparison with predicate:

Similarities		
Item	*UA-Cellular™ for IQ*	*Cell-Chex Auto*
Intended use	Used as an assayed cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment parameters.	Used as an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.
Reagent composition	Stabilized human red and white blood cells combined with non-squamous simulated epithelial and crystal components.	Stabilized human red and white blood cells.
Open vial stability	30 days	Same
Closed vial stability	60 days	75 days
Storage temperature	$2 - 10^o$ C	Same

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

Not Applicable.

L. Test Principle:

Daily use of this whole blood control provides quality control data for confirming the precision and accuracy of instrument operation. Use of stabilized cell preparations for controlling laboratory testing protocols is an established procedure. When handled like a patient sample and assayed on a properly calibrated and functioning instrument the whole blood control will provide values within the expected range indicated on the assay sheet.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. *Precision/Reproducibility:*

    Run-to-Run reproducibility studies were performed on three lots of each level. Each value was calculated from 10 consecutive analyses performed on a single vial of each. Reproducibility is expressed as a CV%, which is calculated by dividing the standard deviation by the mean value and multiplying by 100.

b. Linearity/assay reportable range:

Not applicable.

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

Value assignment: Assay values are assigned to each lot by replicate analysis. A minimum of three vials per level are tested on the IRIS IQ 200. Each vial is tested for a minimum of three test events performed on different dates. Off-site (referee) laboratories are used to supplement data collection for in-house instrumentation or provide unique system specific data. Referees are requested to run each vial in duplicate.

A ten run reproducibility event is run using a vial from each level on the IRIS IQ 200 in addition to the test listed above.

The data is entered into the validated QC link database program which calculates mean, standard deviation, and coefficient of variation for each parameter analyzed. Final assay assignment values are determined using the data collection and established product performance characteristics.

Open vial stability: Level 1 and Level 2 from three lots were run 5 times during the 30 day period to establish open vial stability. On the week days the vials were not run they were brought to room temperature, mixed and opened. Each vial was returned to refrigerated storage (2-10°C) between analysis periods. All lots performed as expected, with parameter recovery within the established assay ranges.

Closed vial stability: Level 1 and Level 2 from three lots were run once per week from the ship date to the expiration date. The vials were stored in a monitored refrigerator between 2-10°C between analysis periods. No significant trends occurred and there was consistent recovery of values within the indicated assay range.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

 f. Assay cut-off:

 Not applicable.

2. <u>Comparison studies:</u>

 a. Method comparison with predicate device:

 Not applicable.

 b. Matrix comparison:

 Not applicable.

3. <u>Clinical studies:</u>

 a. Clinical Sensitivity:

 Not applicable.

 b. Clinical specificity:

 Not applicable.

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

 Not applicable.

4. <u>Clinical cut-off</u>**:**

Not applicable.

5. <u>Expected values/Reference range:</u>

The mean and expected assay values provided for each parameter are derived from replicate analyses on calibrated instruments. The assay values are obtained using reagents recommended by instrument manufactures and are to be used for instrument control (they are not absolute assay for calibration). Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits of each parameter. However, the control mean established by the laboratory should fall within the expected range specified for the control. The expected ranges listed represent estimates of variation due to different laboratories instrument calibration, maintenance, and operator technique.

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.