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

A. 510(k) Number:

k131444

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for the following parameters in urine samples: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, color and microscopic determination of RBC, WBC, epithelial cells, casts, bacteria, crystals, and conductivity.

D. Type of Test:

Not applicable

E. Applicant:

Streck

F. Proprietary and Established Names:

UA-Cellular Complete

G. Regulatory Information:

1. Regulation section:
   862.1660, Quality control material, (assayed, and unassayed)

2. Classification:
   Class I, reserved

3. Product code:
   JJW

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use statements below.

2. Indication(s) for use:

   UA-Cellular Complete is an assayed chemistry and cellular urine control for evaluating the accuracy and precision of automated procedures that measure urinary sediment and chemistry parameters on the Sysmex® UF-1000i™ Automated Urine Particle Analyzer and the Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer utilizing the Clinitek Atlas 10 Reagent Pak.

   The list of assayed parameters includes:

   Sysmex UF-1000i: RBC(/µL), WBC(/µL), Epithelial (/µL), Cast, Bacteria (/µL), Crystals, Conductivity (mS/cm)

   Siemens Clinitek Atlas with Atlas 10 Reagent Pak: Glucose (mg/dL), Bilirubin (As Measured), Ketones (mg/dL), Specific Gravity (As Measured), Blood (As Measured), pH (As Measured), Protein (mg/dL), Urobilinogen (EU/dL), Nitrite (As Measured), Leukocytes (As Measured), Color (As Measured), Clarity (As Measured)

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:
   Sysmex® UF-1000i™ Automated Urine Particle Analyzer
   Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer

I. Device Description:

UA-Cellular Complete is an in vitro diagnostic product designed specifically for use with the Siemens Clinitek Atlas Automated Urine Chemistry Analyzer using the Clinitek Atlas 10 Reagent Pak and the Sysmex UF-1000i Automated Urine Particle Analyzer. UA-Cellular Complete is a tri-level control material which contains the following: stabilized mammalian red blood cells (human source) and white blood cells, stabilized bacteria, and simulated urine sediments in a preservative medium. Analyte levels are adjusted with appropriate chemicals. The product is packaged in 4 oz. amber plastic bottles with foil-lined flip-top-caps. All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-s) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using techniques specified by the U.S.
Food and Drug Administration.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   MAS UA Control
   Sysmex UF-1000i with Urinalysis WAM

2. Predicate 510(k) number(s):
   k023928
   k080887

3. Comparison with predicate:

Similarities and Differences			
Item	Device	Predicate 1 (k023928 – MAS UA Control)	Predicate 2 (k080887 – UFII Control)
Intended Use	Same	Same	Assayed control material for evaluating the accuracy and precision of automated procedures that measure urinary analytes
Measurands	Sysmex UF-1000i: RBC, WBC, Epithelial, Cast, Bacteria, Crystals, Conductivity Siemens Clinitek Atlas with Atlas 10 Reagent Pak: Glucose Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, Color, Clarity	Glucose; Bilirubin,Ketones, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte, Creatinine, Color, Appearance, Crystals	RBC, WBC, Epithelial Cells, Cast, Bacteria, Conductivity
Open-Vial Stability	30 days	6 weeks at 18-25°C 3 months at 2-8°C	30 days
Closed-Vial Stability	60 days	2 years	6 months
Reagents	Stabilized mammalian red blood cells and white blood cells, stabilized	UA Control is a liquid stable control material prepared from human urine. Analyte levels	Latex Control Particles

Similarities and Differences			
Item	Device	Predicate 1 (k023928 – MAS UA Control)	Predicate 2 (k080887 – UFII Control)
	bacteria, and simulate urine sediments in a preservative medium. Analyte levels are adjusted with appropriate chemicals.	are adjusted with various pure chemicals and human source materials. UA Control also contains preservatives and stabilizers.	
Storage Conditions	2-10°C	2-8°C	2-10°C

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

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

L. Test Principle:

UA-Cellular Complete is intended to be run by the clinical laboratory to collectively verify the performance attributes (i.e. calibration, precision and accuracy) of the intended instrument platforms, prior to running clinical patient specimens. The comprehensive tri-level UA-Cellular Complete control serves to align six stabilized urine particle types (i.e. red blood cells, white blood cells, cast, crystals, bacteria and epithelial) with the ten urine chemistry parameters.

Level 1-PC Control – Serves as the positive chemistry control for the urine chemistry parameters that do not align with a corresponding urine particle type (i.e. glucose, bilirubin, ketones and urobilinogen).

Level 1-PCM Control – Serves as the positive chemistry control for the urine chemistry parameters that serve to align with a corresponding urine particle type.

Level NC Control – Serves as the true "negative" control for all qualitative and semi-qualitative urine chemistry measurands and the quantitative urine particle types.

UA-Cellular Complete provides values within the expected ranges indicated on the assay sheet.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

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

Value assignment:

Value Assignment for the UA-Cellular® Complete parameters was based on data collected across three external sites and data collected internally at Streck. Data was collected across three separately manufactured lots. Each site involved in testing provided a 10-run reproducibility study for the tri-level control on each lot (n=40 per level). Four instruments of the Siemens® Clinitek Atlas and Sysmex® UF-1000i™ were utilized to collect data. Four operators were used in the value assignment study. Assay data collected met the sponsor's ±3 Standard Deviation requirements.

Stability:

Shelf-Life and Open Vial Stability testing protocols and acceptance criteria were described and found to be adequate.

Shelf-Life – The 60-day claim was verified in real-time stability studies on the Sysmex® UF-1000i™ and Siemens® Clinitek Atlas with all three lots of device.

Open-vial – The open-vial stability claim was verified on both the Sysmex® UF-1000i™ Automated Urine Particle Analyzer and the Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer using the Clinitek Atlas 10 Reagent Pak.

Open-vial stability testing was performed real-time and is 30 days.

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):

   Not applicable

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   Not applicable

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.