DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

STRECK
DEBORAH KIPP
REGULATORY AFFAIRS MANAGER
7002 S. 109TH STREET
LA VISTA NE 68128

February 9, 2017

Re: K170091
Trade/Device Name: UA-Cellular® Complete
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJW
Dated: January 9, 2017
Received: January 10, 2017

Dear Deborah Kipp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k170091

Device Name
UA-Cellular^® Complete

Indications for Use *(Describe)*

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 following instruments and testing methods: Sysmex® UF-1000i™ Automated Urine Particle Analyzer; Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer utilizing the Clinitek Atlas 10 Reagent Pak; the Arkray AUTION HYBRID™ AU-4050 fully-automated integrated urine analyzer; utilizing the Aution sticks 10EA Reagent strips; Siemens Clinitek Status® line of automated chemistry strip reader analyzers; Manual Reading of Urine Refractive Index; Manual Reading of the Siemens Multistix® 10SG Reagent Strips, and the Siemens Clinitest® hCG Pregnancy test.

The list of assayed parameters includes:

Sysmex^® UF-1000i™: RBC(/µL), WBC(/µL), Epithelial (/µL), Cast (/µL), Bacteria (/µL), Crystals

Arkray AU-4050: RBC(/µL), WBC(/µL), Epithelial (/µL), Cast (/µL), Bacteria (/µL), Crystals

Arkray AU-4050 with Aution sticks 10EA Reagent strips : 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), Turbidity (As Measured)

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)

Siemens Clinitek Status System line with Multistix 10SG Reagent Strips: Glucose (mg/dL); Bilirubin (As Measured), Ketones (mg/dL), Specific Gravity (As Measured), Blood (As Mesured), pH (As Measured), Protein (mg/dL), Urobilinogen (EU/dL), Nitrite (As Measured), Leukocytes (As Measured)

Siemens Multistix 10SG Reagent Strips: 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)

Siemens Clinitest hCG Pregnancy Test Cassette: Pregnancy hCG (As Measured)

Manual Confirmatory Testing: Refractive Index (nD)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Submitter: Streck
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Deborah Kipp, Regulatory Affairs Manager
Address: 7002 South 109th Street; La Vista, NE 68128
Phone: 402-537-5215
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Date Prepared: December 31, 2016

Names

Trade Name: UA-Cellular Complete
Common Name: Quality Control Material (Assayed and Unassayed)
Classification Name: Urinalysis Control
Product Code: JJW (862.1660)
Panel: Clinical Chemistry

Predicate Device:

UA-Cellular Complete (K131444)

Intended 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 following instruments and testing methods: Sysmex® UF-1000i™ Automated Urine Particle Analyzer; Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer utilizing the Clinitek Atlas 10 Reagent Pak; the Arkray AUTION HYBRID™ AU-4050 fully-automated integrated urine analyzer; utilizing the Aution sticks 10EA Reagent strips; Siemens Clinitek Status® line of automated chemistry strip reader analyzers; Manual Reading of Urine Refractive Index; Manual Reading of the Siemens Multistix® 10SG Reagent Strips, and the Siemens Clinitest® hCG Pregnancy test.

The list of assayed parameters includes:

Sysmex® UF-1000i™: RBC(/µL), WBC(/µL), Epithelial (/µL), Cast (/µL), Bacteria (/µL), Crystals

Arkray AU-4050: RBC(/µL), WBC(/µL), Epithelial (/µL), Cast (/µL), Bacteria (/µL), Crystals

Arkray AU-4050 with Aution sticks 10EA Reagent strips : 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), Turbidity (As Measured)

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)

Siemens Clinitek Status System line with Multistix 10SG Reagent Strips: Glucose (mg/dL); Bilirubin (As Measured), Ketones (mg/dL), Specific Gravity (As Measured), Blood (As Mesured), pH (As Measured), Protein (mg/dL), Urobilinogen (EU/dL), Nitrite (As Measured), Leukocytes (As Measured)

Siemens Multistix 10SG Reagent Strips: 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)

Siemens Clinitest hCG Pregnancy Test Cassette: Pregnancy hCG (As Measured)

Manual Confirmatory Testing: Refractive Index (nD)

Description:
UA-Cellular® Complete is a three-level, in-vitro diagnostic, assayed urinalysis control that contains the following: stabilized mammalian red blood cells 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 a 4 oz. amber plastic bottle with a foil-lined flip-top cap. The product must be stored at 2-10°C.

Comparison to Predicate Device:

	UA-Cellular Complete (K131444) Predicate Device	**UA-Cellular Complete- Candidate Device**	**Same or Differences**
Intended Use Statement	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)	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 following instruments and testing methods: Sysmex® UF-1000i™ Automated Urine Particle Analyzer; Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer utilizing the Clinitek Atlas 10 Reagent Pak; the Arkray AUTION HYBRID™ AU-4050 fully-automated integrated urine analyzer; utilizing the Aution sticks 10EA Reagent strips; Siemens Clinitek Status® line of automated chemistry strip reader analyzers; Manual Reading of Urine Refractive Index; Manual Reading of the Siemens Multistix® 10SG Reagent Strips, and the Siemens Clinitest® hCG Pregnancy test. The list of assayed parameters includes: <u>Sysmex® UF-1000i</u>:RBC(/µL), WBC(/µL), Epithelial (/µL), Cast (/µL), Bacteria (/µL), Crystals <u>Arkray AU-4050</u>: RBC(/µL), WBC(/µL), Epithelial (/µL), Cast (/µL), Bacteria (/µL), Crystals <u>Arkray AU-4050 with Aution sticks 10EA Reagent strips</u> : 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), Turbidity (As Measured) <u>Siemens® Clinitek Atlas with Atlas 10 Reagent Pak:</u> 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) <u>Siemens Clinitek Status System line with Multistix 10SG Reagent Strips:</u> Glucose (mg/dL); Bilirubin (As Measured), Ketones (mg/dL), Specific Gravity (As Measured), Blood (As Mesured), pH (As Measured), Protein (mg/dL), Urobilinogen (EU/dL), Nitrite (As Measured), Leukocytes (As Measured) <u>Siemens Multistix 10SG Reagent Strips:</u> 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) <u>Siemens Clinitest hCG Pregnancy Test Cassette</u>: Pregnancy hCG (As Measured) <u>Manual Confirmatory Testing:</u> Refractive Index (nD)	Addition of Arkray AU-4050 Addition of Arkray AU-4050 with Aution sticks 10EA Reagent Strips Addition of Siemens Clinitek Status System line with Multistix 10SG Reagent Strips Addition of Siemens Multistix 10SG Reagent Strips Addition of Siemens Clinitest hCG Pregnancy Test Cassette Addition of Manual Confirmatory Testing-Refractive Index <u>Note</u>: Conductivity will now be included only for use by Service personnel only.

Open Vial Stability	30 days	30 days	Same
Closed Vial Stability	60 days	100 days	Increase in Closed-Vial Stability to 100 days
Reagents	Stabilized mammalian red blood cells and white blood cells, stabilized bacteria, and simulate urine sediments in a preservative medium. Analyte levels are adjusted with appropriate chemicals.	Stabilized mammalian red blood cells and white blood cells, stabilized bacteria, and simulated urine sediments in a preservative medium. Analyte levels are adjusted with appropriate chemicals.	Same
Storage Conditions	2 - 10˚C	2 - 10˚C	Same

Discussion of Tests and Test Results:

To substantiate the product performance claims for UA-Cellular Complete, Streck collected product performance data for the following studies: Multi-Site Precision Study, Single-Site Precision Study, Open-Vial Stability and Closed-Vial Stability. Throughout all tests, the product was stored in accordance with the IFU at the recommended temperature of 2 - 10˚C. Specific details of each test are included below:

Multi-Site Precision Study
Two precision studies were executed for UA-Cellular complete. One for the instruments that report values for the cellular parameters and one for the qualitative and semi-quantitative instruments and methods that report values for the chemistry parameters.

Cellular Instrument Study
This multi-site precision study was collected for the Sysmex UF1000i and Arkray AU4050. This study was conducted per EP05-A3 across 3 instruments at three different sites. A single operator was used at each site for data collection. Each site ran each lot and level of control for 5 days, 2 runs per day, and 3 replicates per run.

Chemistry Instrument Study
This multi-site precision study was conducted utilizing the following chemistry instruments/manual methods:

- Siemens CLINITEK Atlas Utilizing the CLINITEK Atlas 10 Reagent Pak
- Siemens Status System Line Utilizing the CLINITEK Multistix 10SG Reagent Strips
- Arkray AUTION HYBRID AU-4050 Utilizing the AUTION Sticks 10EA Reagent Strips
- Manual Reading of the Siemens Multistix 10SG Reagent Strips
- Manual Reading of the Siemens Clinitest hCG Pregnancy Test Cassette
- Manual Confirmatory Testing (Refractive Index)

Three instruments/sites were used. If there were more than one instrument at a site, each was physically separated and a separate operator was used.

Each site was instructed to run at minimum one 10-run reproducibility study. The data received was compared to the range/concentration determined for each level.

Single-Site Precision Study

Single site precision studies were conducted for the cellular and chemistry instruments/methods.

Cellular instrument Study

This study was combined with the Closed-Vial Stability study for both the UF-1000i and Arkray AU4050 instruments. The study was conducted per the guidelines contained in CLSI EP05-A3, Chapter 3, *Single-Site Precision Evaluation Study*.

This study was conducted with three separately manufactured lots of control on both the UF-1000i and Arkray AU4050. Data was collected internally at Streck. The 20x2x2 model was followed for this study. Two vials of control were used for each testing interval. Each vial of control was run in duplicate. The study was repeated for each lot and level of control. Data was analyzed per CLSI EP05-A3 guidelines.

Chemistry Instruments/Manual Methods Study

A single-site study was also conducted for all of the instruments and manual methods for the chemistry measurands. Three separately manufactured lots of control were used for this study. Data was collected internally at Streck. The 20x2x2 model was followed for this study. Two vials of control were used for each testing interval. Each vial of control was run in duplicate. The study was completed for each lot and level of control.

Data was collected for the following instruments:

- Siemens CLINITEK Atlas Utilizing the CLINITEK Atlas 10 Reagent Pak
- Siemens Status System Line Utilizing the CLINITEK Multistix 10SG Reagent Strips
- Arkray AUTION HYBRID AU-4050 Utilizing the AUTION Sticks 10EA Reagent Strips
- Manual Reading of the Siemens Multistix 10SG Reagent Strips
- Manual Reading of the Siemens Clinitest hCG Pregnancy Test Cassette
- Manual Confirmatory Testing (Refractive Index)

Open-Vial Stability Study
An open-vial stability study was conducted for both the cellular and chemistry instrument methods. All studies were conducted real-time for the 30-day open-vial stability claim.

Cellular Instrument Study
This study was conducted with three separately manufactured lots of control on the UF-1000i and Arkray systems. One vial of control per level from each lot was analyzed over the 30-day open-vial stability plus one additional time point beyond the 30-day claim. Data was collected internally with one operator. Four replicates were taken during each testing event. Throughout the collection of the open-vial stability data each vial of control was stored in accordance with the IFU. Each vial was stored between 2° to 10°C and removed from the refrigerator for testing. After testing, the vial was returned to the refrigerator until the next testing event

This study was conducted with three separately manufactured lots of control for each representative instrument/method. One vial of control per level from each lot was analyzed over the 30-day open-vial stability plus an additional time point beyond the stated stability claim. Day 0 is the baseline value observed on the first day of the study. The last test point was collected after the stated open-vial stability claim to ensure that the claim was fully encompassed. Four replicates were taken during each testing event.

Data was collected utilizing the following instruments:

- Siemens CLINITEK Atlas Utilizing the CLINITEK Atlas 10 Reagent Pak
- Siemens Status System Line Utilizing the CLINITEK Multistix 10SG Reagent Strips
- Arkray AUTION HYBRID AU-4050 Utilizing the AUTION Sticks 10EA Reagent Strips
- Manual Reading of the Siemens Multistix 10SG Reagent Strips
- Manual Reading of the Siemens Clinitest hCG Pregnancy Test Cassette
- Manual Confirmatory Testing (Refractive Index)

Throughout the collection of the open-vial stability data each vial of control was stored in accordance with the IFU. Each vial was stored between 2° to 10° C and removed from the refrigerator for testing. After testing, the vial was returned to the refrigerator until the next testing event.

Data for the cellular study was determined to be acceptable if the mean of each run was within the acceptable range of control. Data for the chemistry study was considered acceptable if it was in agreement with the assigned range/concentration. All data collected fell within the acceptance criteria established for each instrument.

Closed-Vial Stability

A closed-vial stability study was conducted for both the cellular and chemistry instrument methods. All studies were conducted real-time for the 100-day closed-vial stability claim.

Cellular instrument study

This study was conducted with three separately manufactured lots of control on the UF-1000i and Arkray systems. Two vials of control per level from each lot was analyzed in duplicate over the 100-day closed-vial stability plus one additional time point beyond 100 days. Four data points were collected at each testing event. Data was collected internally with one operator. Each vial was stored between 2° to 10° C and removed from the refrigerator for testing. After testing, the vial was returned to the refrigerator until the next testing event.

Chemistry Instrument Study

This study was conducted with three separately manufactured lots of control for each representative instrument/method. One vial of control per level from each lot was analyzed over the 100-day closed-vial stability plus an additional time point beyond the stated stability claim. Day 0 is the baseline value observed on the first day of the study. The last test point was collected after the stated closed-vial stability claim to ensure that the claim was fully encompassed. Four replicates were taken during each testing event.

The following instruments were utilized for this study:

- Siemens CLINITEK Atlas Utilizing the CLINITEK Atlas 10 Reagent Pak
- Siemens Status System Line Utilizing the CLINITEK Multistix 10SG Reagent Strips
- Arkray AUTION HYBRID AU-4050 Utilizing the AUTION Sticks 10EA Reagent Strips
- Manual Reading of the Siemens Multistix 10SG Reagent Strips
- Manual Reading of the Siemens Clinitest hCG Pregnancy Test Cassette
- Manual Confirmatory Testing (Refractive Index)

Data for the cellular study was determined to be acceptable if the mean of each run was within the acceptable range of control. Data for the chemistry study was considered acceptable if it was in agreement with the assigned range/concentration. All data collected fell within the acceptance criteria established for each instrument.

The resultant data set established that UA-Cellular Complete is safe and effective for its intended use and that the product is stable for the entire product dating. The product fulfills its intended use as instructed in the Instructions for Use.

Conclusions Drawn From Tests:

Study results show UA-Cellular Complete to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. UA-Cellular Complete is a safe and effective product, which fulfills its intended use when used as instructed in the Instructions for Use.