K 131444

510(k) Summary

JAN 29 2014

510(k) Submitter:	Streck 7002 South 109th Street Omaha, NE 68128
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Date Prepared:	Revised: January 28, 2014

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:

Primary Predicate- MAS UA Control (K023928)

Secondary Predicate- Sysmex UF II CONTROL™-K080887
Note: This product was cleared with the 510(k) for the Sysmex UF-1000i instrument (K080887)

Intended Use:

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 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)

Description:
UA-Cellular® Complete is an in-vitro diagnostic product 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:

	MAS UA Control (K023928)-Primary Predicate	**UFII Control (K080887)* - Secondary Predicate**	**UA-Cellular Complete**
Intended Use	MAS UA Control is intended for use in the clinical laboratory as a control for qualitative and semi-quantitative procedures used in routine urinalysis testing. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and equipment. The product is suitable for use as a control material for physiochemical, chemical, and microscopic methods of routine urinalysis. UA Control may be used in conjunction with commercially available urine microscopic analysis	UF II CONTROL contains control particles for use in quality control mode of the Sysmex Fully Automated Urine Particle Analyzer (UF-1000i and UF-500i) and Fully Automated Integrated Urine Analyzer (UX-2000) *Note-UFII Control Information was submitted with the 510(k) for the UF-1000i instrument.	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) Note: Alternate units are provided on the product assay sheet.

	MAS UA Control (K023928)-Primary Predicate	UFII Control (K080887)* - Secondary Predicate	UA-Cellular Complete
Assayed Parameters	Glucose(mg/dL); Bilirubin(As Measured),Ketones (As Measured), Specific Gravity (As Measured), Blood (As Measured), pH (As Measured), Protein (As Measured), Urobilinogen EU/dL), Nitrite (As Measured), Leukocyte (As Measured), Creatinine (mg/dL), Color (As Measured), Appearance (As Measured), Crystals (As Measured)	RBC (/µL), WBC (/µL), Epithelial Cells(/µL), Cast (/µL), Bacteria (/µL), Conductivity (mS/cm)	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)
Open-Vial Stability	6 weeks at 18-25°C 3 months at 2-8°C	30 days	30 days
Closed-Vial Stability	2 years	6 months	60 days
Reagents	UA Control is a liquid stable control material prepared from human urine. Analyte levels are adjusted with various pure chemicals and human source materials. UA Control also contains preservatives and stabilizers.	Latex Control Particles	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.
Storage Conditions	2-8°C	2-10°C	2-10°C

Discussion of Tests and Test Results:

To substantiate the product performance claims for UA-Cellular Complete on the Sysmex® UF-1000i™ Automated Urine Particle Analyzer and Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer utilizing the Clinitek Atlas 10 Reagent Pak, Streck collected product performance data for the following studies: Value Assignment, Open-Vial Stability, Closed-Vial Stability, and Precision Performance. Specific details regarding each study are included below:

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 ±3 Standard Deviation requirements.

Open –Vial Stability

Open-vial stability testing was based on data collected real time across three separately manufactured lots. All data was collected internally at Streck utilizing one operator. A single instrument of the Siemens® Clinitek Atlas and Sysmex® UF-1000i™ were utilized to collect data. Data collection began on day 30 after the product release date. Values collected over the last 30-days of product dating were compared to the assayed values assigned on Day 0 before product release. All values collected were within the assigned assay range.

Closed-Vial Stability

The 60-day Closed-Vial Stability claim was verified utilizing three-separately manufactured lots of control. All data was collected internally at Streck utilizing one operator. A single instrument of the Siemens® Clinitek Atlas and Sysmex® UF-1000i™ were utilized to collect data. Data collected was within the documented assay ranges.

Precision Performance

Precision performance testing for UA-Cellular Complete was based on the data collected at three external sites and data collected internally at Streck. Data was collected across three separately manufactured lots. Each site provided a 10-run reproducibility study for the tri-level control (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 Precision Performance study. All data for this study fell within the assigned assay values for the product.

These tests 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.

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

January 29, 2014

STRECK
DEBORAH KIPP
QUALITY ASSURANCE COORDINATOR
7002 SOUTH 109TH ST.
OMAHA NE 68128

Re: K131444
Trade/Device Name: UA-Cellular Complete
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJW
Dated: December 18, 2013
Received: December 19, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Courtney H. Lias -S

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 on last page.

510(k) Number *(if known)*
K131444

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 Sysmex® UF-1000i™ Automated Urine Particle Analyzer and the Siemens® Clinitek Atlas Automated Urine Chemistry Analyzer utilizing the Clinitek Atlas 10 Reagent Pak.

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S