K121456

arkray

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510(k) Summary

Date Prepared: January 18th, 2013

Submitter: ARKRAY Factory USA, Inc.
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Device Name and Regulatory Information

Trade Name:
1. ARKRAY AUTION™ HYBRID AU-4050 Fully Automated Integrated Urine Analyzer System
2. AUTION™ Control Solution
3. Uriflet™ S 9HA Urinalysis Test Strips

Common Name:
1. Automated Urinalysis System (Class I, Class II), Automated Urine Particle Analyzer (Class II)
2. Urinalysis Controls (Assayed and Unassayed) (Class 1, reserved)
3. Urinalysis Test Strip

Table 1: Regulatory Information

Regulation: 21 CFR Section	Product Code	Classification	Description
862.2900	KQO	Class I	Automated Urinalysis System
864.5200	LKM	Class II	Counter, Urine Particle
862.1660	JJW	Class I, reserved	Urinalysis Controls (Assayed and Unassayed)
862.1340	JIL	Class II	Glucose (Urinary, Non-Quantitative)
864.6550	JIO	Class II	Blood, Occult, Colormetric, In Urine
862.1785	CDM	Class I	Urobilinogen (Urinary Non-Quant.)
862.1550	CEN	Class I	Ph (Urinary, Non-Quant.)
862.1435	JIN	Class I	Ketones (Urinary, Non-Quant.)
862.1645	JIR	Class I	Protein or Albumin (Urinary, Non-Quant.)
862.1115	JJB	Class I	Urinary Bilirubin & Its Conjugates (Urinary, Non-Quant.)
862.1510	JMT	Class I	Nitrite (Urinary, Non-Quant.)
864.7675	LJX	Class I	Test, Urine Leukocyte

862.2900	JRE	Class I	Refractometer for Clinical Use

Predicate Devices

AUTION MAX AX-4030 Urinalysis System (k093098)

SYSMEX UF1000i Automated Urine Particle Analyzer with Urinalysis WAM software (k080887)

Sysmex UF-II Control (k070910)

Device Description

The AUTION HYBRID AU-4050 is a fully automated urine analysis system. The AU-4050 contains a test strip chemistry urine analyzer also called the chemistry module (CHM) and a flow cytometry urine particle analyzer also called the flow cytometry module (FCM) together in a single integrated device. The CHM module analyzes the following parameters in urine: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, and color. The FCM module measures the following parameters in urine utilizing flow cytometry technology: Red Blood Cells, White Blood Cells, Epithelial Cells, Casts, and Bacteria. The FCM module flags for the presence of the following: Pathologic Casts, Crystals, Sperm, Small Round Cells, Yeast Like Cells and Mucus.

Indications for Use

AUTION HYBRID™ AU-4050 Fully Automated Integrated Urine Analyzer System

The AUTION HYBRID™ AU-4050 Fully Automated Integrated Urine Analyzer System contains a test strip chemistry urine analyzer and a flow cytometry urine particle analyzer together in a single integrated device. The test strip chemistry module (CHM) is an automated urine analyzer intended for the in vitro measurement of the following parameters: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, and color. The chemistry module is intended for use with the Uriflet™ S 9HA multi-parameter urine chemistry test strips. The flow cytometry module (FCM) is an automated urine particle analyzer intended to analyze the following parameters in urine samples: Red Blood Cells, White Blood Cells, Epithelial Cells, Casts, and Bacteria and flags the presence of the following: Pathologic Casts, Crystals, Sperm, Small Round Cells, Yeast Like Cells, and Mucus. The AUTION HYBRID AU-4050 is intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

AUTION™ Control Solution

The AUTION Control Solution is intended for in vitro diagnostic use only for performing quality control procedures with the AUTION HYBRID AU-4050 flow cytometry module.

Uriflet S 9HA Urinalysis Test Strips

Uriflet™ S 9HA is a urinalysis test strip with reagent pads for the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketones, Nitrite, and Leukocytes. Uriflet S 9HA is for use with the AUTION HYBRID AU-4050 only.

Comparison to Predicate Devices

A comparison of the ARKRAY AUTION HYBRID AU-4050 Fully Automated Integrated Urine Analyzer System to the predicate devices indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features

The comparison matrices presented below clearly demonstrate that the proposed AU-4050 device is substantially equivalent to the AX-4030 and UF-1000i devices; and the AUTION Control Solution is substantially equivalent to the UF-II Control with regard to the following important aspects:

- Intended Use
- Fundamental Technology
- Performance Specifications

TABLE 1 below is a comparison between the AUTION HYBRID AU-4050 Fully Automated Integrated Urine Analzer System and the AUTION MAX AX-4030 Urinalysis System (k093098) used for urine chemistry analysis.

TABLE 2 below is a comparison between the AUTION HYBRID AU-4050 Fully Automated Integrated Urine Analzer System and the Sysmex UF-1000i Urine Particle Analyzer with Urinalysis WAM software (k080887) used for urine sediment analysis.

TABLE 3 below is a comparison between the AUTION Control Solution and the Sysmex UF-II Control solutions used for quality control purposes on the FCM unit of the AUTION HYBRID AU-4050.

TABLE 1 Substantial Equivalence Comparison Table		
Category	**AX-4030 (Predicate device-k093098)**	**AU-4050 (proposed device)**
Intended Use	Automated urine chemistry analyzer for the *in vitro* measurement of urine chemistry analytes.	Same
Sample Type	Human Urine	Same
Sample Volume	2 mL	5 mL
Measurement Wavelength	430, 500, 565, 635, 760 nm	Same
Measurement Method	Operating Principle: Spectrophotometery Test Strip: Dual-wavelength reflectance measurement (Single wavelength for BLD) S.G.: Reflection refractometry Color Tone: Light-transmission measurement Turbidity: Light-scattering measurement	Same
Measurement Items	GLU, PRO, BIL, URO, PH, BLD, KET, NIT, LEU, S.G, turbidity and color-tone	Same
Test Strip Reaction Time	Approx. 60 seconds	Same as AX-4030
Processing Speed	225 samples/hr	200 samples/hr (CHM mode); 100 samples/hr (CHM + FCM mode)
Display	Large color liquid crystal display (320 x 240 dots)	IPU computer screen
Built-in Printer	Yes	Yes
External Output	RS-232C/Ethernet	Same
Supply Voltage	100-240 VAC, 50/60 Hz	Same
Site Location	For indoor use only	Same
Dimensions (mm)	530 (W) x 530 (D) x 530 (H)	800 (W) x 720 (D) x 720 (H)
Physical Layout	-Analyzer -Sampler	Same
Weight	Approx. 41 kg	Approx. 120 kg

TABLE 2 Substantial Equivalence Comparison Table		
Category	**UF-1000i (Predicate device-k080887)**	**AU-4050 (proposed device)**
Intended Use	Automated urine particle analyzer for the *in vitro* measurement of urine sediments.	Same
Sample Type	Human Urine	Same
Sample Volume	3 mL	5 mL
Measurement Wavelength	N/A	Same
Measurement Method	The device utilizes Sysmex flow cytometry using a red semiconductor laser for analyzing organized elements or urine. Particle characterization and identification is based on detection of forward scatter, fluorescence, and adaptive cluster analysis. The UF-1000i uses the addition of a new bacteria channel and side scatter light signal.	Same
Measurement Items	RBC, WBC, Epithelial Cells, Cast, and Bacteria and flags the presence of the following: Pathologic Cast, Crystal, Sperm, Small Round Cell, Yeast like cell and Mucus.	Same
Test Strip Reaction Time	N/A	Same as AX-4030
Processing Speed	100 samples/hr	200 samples/hr (CHM mode); 100 samples/hr (CHM + FCM mode)
Display	IPU computer screen	IPU computer screen
Built-in Printer	No	Yes
External Output	RS-232C/Ethernet	Same
Supply Voltage	100-240 VAC, 50/60 Hz	Same
Site Location	For indoor use only	Same
Dimensions (mm)	580 (W) x 710 (D) x 615 (H)	800 (W) x 720 (D) x 720 (H)
Physical Layout	-Analyzer -Sampler	Same
Weight	Approx. 75.5 kg	Approx. 120 kg

TABLE 3 Substantial Equivalence Comparison Table		
Category	**Sysmex UF-II Control (Predicate device-k070910)**	**AUTION Control Solution (Proposed device)**
Intended Use	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)	The AUTION Control Solution is intended for in vitro diagnostic use only for perfroming quality control procedures with the AUTION HYBRID AU-4050 flow cytometry module.
Form	Liquid, ready to use	Same
Levels	2	Same
Storage Stability	2°C-10°C until expiration date	Same
Open Vial Stability	30 days at 2°C-10°C	Same
Matrix	Liquid matrix solution	Same
Analytes	Red Blood Cells, White Blood Cells, Epithelial Cells, Casts, and Bacteria	Same

Summary of Performance Data

Clinical and bench testing was used to verify the performance characteristics of this device. This testing showed acceptable device performance that is substantially equivalent to the performance of the predicate devices.

Conclusion

Based upon the indications for use, comparison with the previously cleared predicate devices, technology and verification testing, ARKRAY has determined that the AUTION HYBRID AU-4050 described in this submission has been shown to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 1, 2013

ARKRAY, Inc.
c/o Adam Ettl
5182 West 76th Street
Edina, Minnesota 55439

Re: k121456
Trade/Device Name: AUTION HYBRID™ AU-4050 Fully Automated Integrated Urine Analyzer System; Uriflet™ S 9HA Urine Test Strips; AUTION Control Solution
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: JIO, KQO, LKM, JJW, JIL, CDM, JJB, JIN, JIR JMT, LJX, CEN, JRE
Dated: December 18, 2012
Received: December 19, 2012

Dear Mr. Ettl,

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.

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 Part 801); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson 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

Indications for Use

510(k) Number: k121456

Device Name: AUTION HYBRID™ AU-4050 Fully Automated Integrated Urine Analyzer System

Uriflet™ S 9HA Urine Test Strips

AUTION™ Control Solution

Indications for Use:

AUTION HYBRID™ AU-4050 Fully Automated Integrated Urine Analyzer System

The AUTION HYBRID™ AU-4050 Fully Automated Integrated Urine Analyzer System contains a test strip chemistry urine analyzer and a flow cytometry urine particle analyzer together in a single integrated device. The test strip chemistry module (CHM) is an automated urine analyzer intended for the in vitro measurement of the following parameters: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity, and color. The chemistry module is intended for use with the Uriflet™ S 9HA multi-parameter urine chemistry test strips. The flow cytometry module (FCM) is an automated urine particle analyzer intended to analyze the following parameters in urine samples: Red Blood Cells, White Blood Cells, Epithelial Cells, Casts, and Bacteria and flags the presence of the following: Pathologic Casts, Crystals, Sperm, Small Round Cells, Yeast Like Cells, and Mucus. The AUTION HYBRID AU-4050 is intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

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Indications for Use

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Uriflet™ S 9HA Urine Test Strips

Uriflet™ S 9HA is a urinalysis test strip with reagent pads for the determination of Glucose, Protein, Bilirubin, Urobilinogen, pH, Blood, Ketones, Nitrite, and Leukocytes. Uriflet S 9HA is for use with the AUTION HYBRID AU-4050 only.

AUTION™ Control Solution

The AUTION Control Solution is intended for in vitro diagnostic use only for performing quality control procedures with the AUTION HYBRID AU-4050 flow cytometry module.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Ruth A. Chesler

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