510(k) Summary

K101852

MAR 2 3 2011

Applicant:
Iris Diagnostics, a Division of IRIS International Inc
9172 Eton Avenue
Chatsworth, CA 91311
(818) 709-1244
David W. Gates, Ph.D. VP Quality Assurance and Regulatory Affairs

I. iChem VELOCITY Automated Urine Chemistry System

Proprietary and Established Names:

Proprietary names: iChem® VELOCITY™ Automated Urine Chemistry System and iChem® VELOCITY™ Chemistry Strips.

Common names: Automated Urinalysis System, Urinary Test System (non-quantitative).

Regulation Section:	Code	Test
21 CFR § 862.2900	KQO	Automated Urinalysis System
21 CFR § 862.1340	JIL	Urinary Glucose (Non Quantitative) Test System
21 CFR § 864.6550	JIO	Occult Blood test
21 CFR § 862.1785	CDM	Urinary Urobilinogen (Non-Quantitative)
21 CFR § 862.1550	CEN	Urinary pH (Non-Quantitative) Test System
21 CFR § 862.1510	JMT	Nitrite (Non-Quantitative) Test System
21 CFR § 862.2800	JRE	Refractometer for Clinical Use
21 CFR § 864.7675	LJX	Leukocyte Peroxidase Test
21 CFR § 862.1095	JMA	Ascorbic Acid Test System
21 CFR § 862.1435	JIN	Ketones (Non-Quantitative) Test System
21 CFR § 862.1645	JIR	Urinary Protein or Albumin (Non-Quant.) Test System
21 CFR § 862.1115	JJB	Urinary Bilirubin and its conjugates (Non-Quantitative) Test System

Classification names: Automated Urinalysis System; Urinary Test Systems (Non Quantitative); Refractometer for Clinical Use

Class II: Urinary Glucose and Occult Blood

Class I: Automated Urinalysis System, Urinary Urobilinogen, Urinary pH, Ketones, Urinary Protein, Urinary Bilirubin, Nitrite, Leukocyte Peroxidase, Ascorbic Acid, Refractometer.

Indication For Use:

The iChem®VELOCITY™ automated urine chemistry system is an in vitro diagnostic device used to automate the urine chemistry analysis profile using iChem®VELOCITY™ Urine Chemistry Strips. The iChem VELOCITY can be used as a stand alone-system, as well as in an iQ®200 Series system, a configuration given the proprietary name iRICELL™ as it is designed to be hardware and software compatible with iQ200 Series systems. It produces quantitative results for specific gravity, semi-quantitative results for glucose, blood, leukocyte esterase, bilirubin, urobilinogen, pH, protein, ketones and ascorbic acid; and qualitative results for nitrites, color and clarity. iChemVELOCITY strips are intended for use only with the iChemVELOCITY analyzer. In particular they are not

intended for visual reading. The iChem VELOCITY test strips are not intended for visual reading. The iChemVELOCITY is not intended to be used as a Point of Care (POC) analyzer.

These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function. Tests performed using the iChem VELOCITY are intended for clinical laboratory use and in vitro diagnostic use only.

Devices to which substantial equivalence is claimed

iChem 100 Urine Chemistry Analyzer and iChem 10SG strips

Description of the proposed device:

The proposed device is a fully automated, computer-controlled urine chemistry analyzer intended for use only with iChemVelocity Chemistry Strips for the measurement of ten urine chemistry analytes from the chemistry strip plus the measurement of specific gravity using an electronic refractometer assembly and the qualitative measurement of color and clarity by optical absorbance and scattering methods, respectively.

	Proposed	Predicate
Device	**iChem VELOCITY, iChem VELOCITY strips**	**iChem 100 Analyzer 10SG strips**
Intended use	The iChem®VELOCITY™ automated urine chemistry system is an in vitro diagnostic device used to automate the urine chemistry analysis profile using iChem®VELOCITY™ Urine Chemistry Strips. The iChem VELOCITY can be used as a stand alone-system, as well as in an iQ®200 Series system, a configuration given the proprietary name iRICELL™ as it is designed to be hardware and software compatible with iQ200 Series systems. It produces quantitative results for specific gravity, semi-quantitative results for glucose, blood, leukocyte esterase, bilirubin, urobilinogen, pH, protein, ketones and ascorbic acid; and qualitative results for nitrites, color and clarity. iChemVELOCITY strips are intended for use only with the iChemVELOCITY analyzer. In particular they are not intended for visual reading. The iChem VELOCITY test strips are not intended for visual reading. The iChemVELOCITY is not intended to be used as a Point of Care (POC) analyzer. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function. Tests performed using the iChem VELOCITY are intended for clinical laboratory use and in vitro diagnostic use only.	The iChem100 is a semi-automated urine analyzer intended for the *in vitro* measurement of the following analytes: glucose (GLU), protein (PRO), bilirubin (BIL), urobilinogen (URO), pH, blood (BLD), ketones (KET), nitrite (NIT), leukocytes (LEU), specific gravity (SG) and color.

Design	1. Uses similar well-proven design methods as predicate.	1. Uses well-proven chemistry strip methods, and optical absorbance and scattering for determination of analytes in and physical properties of urine.
	2. Same as predicate	2. Is capable of stand-alone, as well as joint operation with an Iris iQ200 Series System.
	3. Same as predicate	3. Tests for the concentration of ascorbic acid in urine.
	4. Same as predicate	4. Uses fixed-time end-point reflectance for all chemistry determinations.
	5. Same as predicate	5. LED's with three different wavelengths are used to illuminate the test strips for measurement. It utilizes a (CMOS) image sensor that captures a color image of each of the test pads. The CMOS image sensor is able to photograph almost the whole length (100mm) of the urine test strip and all of its width.
	6. Urine color is measured by the absorbance of white light through a flowcell containing urine. Intensities of RGB wavelengths are measured with a solid-state photodetector array.	6. Urine color is measured from the color compensation pad on the iChem 10 SG strip
	7. Specific gravity is measured by determining the refractive index of the specimen.	7. Specific Gravity is measured using a test pad that contains a detergent and Bromthymol blue that indicates the presence of ionic constituents in the urine by changing color from green to yellow. The test pad for specific gravity is impregnated with a reddish dye so that the color produced is yellow-brown tan.
Energy source	A.C. power is converted to	A.C. power is converted to 7.5

	D.C. by an internal switching mode power supply	VD.C. by an external power converter.
Materials	Materials are generally same as predicate	Commodity materials and purchased components used in most bench top laboratory instruments, i.e. aluminum frames, thermoplastic enclosures and various molded parts; switching mode power supplies, solder-plated printed circuit board assemblies, programmable and general purpose microprocessors, discrete wire harnesses, flat flexible cables etc.
Safety	The proposed device has been certified to comply with latest applicable safety standards for U.S., Canada, and the European Union, including CB Scheme Certificate and Report. Specifically, these include UL61010-1, CAN/CSA C22.2 #61010-1, IEC 61010-1, CENELEC EN61010-1, IEC61010-2-101, and CENELEC EN 61010-2-81	The predicate device was tested to U.S. (U.L.) Part 1: General Requirements, UL61010A-1, First Edition. and to the Canadian Standards for Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use; Part 1: General Requirements, CAN/CSA-C22.2 No. 1010.1-92, First Edition. It was also tested to the European/International versions of those norms IEC 61010-1/ EN 61010-1: 2001 "Safety requirements for electrical equipment for measurement, control, and laboratory use: Part I General requirements"
Electromagnetic Compatibility	The proposed device has been tested and certified to CENELEC EN 61326-1 EMC requirements-general and CENELEC EN 61326-2-6 EMC requirements-particular requirements for IVD medical equipment.	Was tested and certified to IEC61326-1:1997+A1 1998+A2:2001
Chemistry strips	1. The iChem VELOCITY is intended for use only with Iris VELOCITY chemistry strips 2. Analyte detection chemistry composition very similar	1. The iChem100 is intended for use only with the iChem 10 SG multi-parameter test strips. 2. Analyte detection pads for glucose and pH are more hydrophobic.

II. iChem VELOCITY CalChek Kit

Proprietary and Established Names:

Proprietary name: iChem VELOCITY CalChek Kit

Classification name: Quality control material (assayed and unassayed).

Common name: Urinalysis controls

Regulation Section:	**Code**	**Test**
21 CFR § 862.1660	JJX	Single (Specified) Analyte Controls (Assayed And Unassayed)

Class I: Single (Specified) Analyte Controls, Assayed.

Unclassified: Urinary Color, Urinary Clarity (Turbidity)

Device to which substantial equivalence is claimed
IRISpec Gravity Control 1™ and IRISpec Gravity Control 2™
File No. K960054

Arkray Check Strips
K013783

Description of the proposed device:
iChem VELOCITY CalChek Reagents are a set of buffer-based solutions intended for the in vitro monitoring of specific gravity, color and clarity.

Intended Use:

The iChem®VELOCITY™ CalChek Kit is a set of assayed and unassayed *in vitro* diagnostic controls for monitoring performance of the iChem VELOCITY urine chemistry analyzer.

The controls include assayed liquid controls for the monitoring of the specific gravity measurement module, and unassayed liquid color and clarity controls for the monitoring of color and clarity measurements. The kit also includes a set of assayed reflectance strips for the monitoring of reflectance measurements.

These measurements monitored by these controls are part of an automated urine chemistry analyzer used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function.

Comparison of the proposed device with the predicate device

Comparison	**iChem VELOCITY Specific Gravity Calcheks (Proposed Device)**	**IRISpec Gravity Control 1™ IRISpec Gravity Control 2™ (Predicate Devices)**
Composition	Glycerol, salts, food dyes, preservative, dissolved in deionized water. No biological material.	Salts, food coloring,glycerin,stabilizers, preservative in deionized water
Form	Same as predicate	Liquid, ready to use

Preservatives	Yes	Yes
Storage	20-28°C (68-82°F)	Dark, dry place (2-8C)
Stability-closed vial	1 year	1 year
Stability-open vial	Single use	30 days
S.G. Cal value -low	1.002 ± 0.002	NA
S.G. Cal value-med	1.030 ± 0.002	1.025 ± 0.001
S.G. Cal value-high	1.060 ± 0.002	1.060 ± 0.001
Intended use	Assayed QC materials for monitoring of urine chemistry specific gravity on the iChem VELOCITY Urine Analyzer.	For IVD use in the operation of IRIS Urinalysis workstations
Analytes	SG at three levels	Specific Gravity at two levels
Usage	Vial is intended for one time use	Contents dispensed for multiple uses
Packaging-container	10 mL Vacutainers	500 mL glass container

Comparison	**IRIS Reflectance Calchecks (Proposed Device)**	**Arkray Check Strips (Predicate Devices)**
Composition	Munsell paper of various reflectances laminated to mylar foil	One plain mylar foil, one laminate
No. sets per package	Same as predicate	2
Reflectance acceptance ranges	Same as predicate	Programmed into instrument
Packaging	Same as predicate	Clear polystyrene cylindrical tube with press-on stopper
No. of strips/set	5	2
Distinct reflectance values	89.8%,72.3%,39.4%, 19.4%,5.8%,	White (90-110%), gray (~30-40)
Measurement wavelengths	472,525,630nm	430,500,565,635,760 nm
Reusable	No	Yes, until results are out of range
Shelf-life	1 year	Not specified
Storage temperature	18-25°C	20-28° C
Package Insert	P/N 300-1226	No

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

IRIS International Inc.
c/o Mr. David Gates
9172 Eton Avenue
Chatsworth, CA 91311

MAR 2 3 2011

Re: k101852
Trade Name: iChem® VELOCITY™ Automated Urine Chemistry System
iChem® VELOCITY™ Chemistry Strips
iChem® VELOCITY™ CalChek Kit
Regulation Number: 21 CFR §862.1340
Regulation Name: Urinary Glucose (non-quantitative test system)
Regulatory Class: Class II
Product Codes: JIL, CDM, JJB, JIN, JIR, JMT, LJX, CEN, JIO, JRE, JMA, KQO
Dated: March 2, 2011
Received: March 4, 2011

Dear Mr. Gates:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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* Diagnostic Device Evaluation and Safety 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,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K101852

Device Names: iChem® VELOCITY ™ Urine Chemistry System

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Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

510(k) Number (if known): k101852

Device Names: iChem® VELOCITY ™ CalChek Kit

Indication For Use: The iChem®VELOCITY™ CalChek Kit is a set of assayed and unassayed *in vitro* diagnostic controls for monitoring performance of the iChem VELOCITY urine chemistry analyzer.

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