



Food and Drug Administration
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May 12, 2017

IRIS DIAGNOSTICS, A DIVISION OF IRIS INTERNATIONAL
NANCY NADLER
DIRECTOR, REGULATORY AFFAIRS
9172 ETON AVE
CHATSWORTH, CA 91311

Re: K171083

Trade/Device Name: iChemVELOCITY Automated Urine Chemistry System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, CDM, JJB, JIN, JIR, JMT, LJX, CEN, JRE, JMA, KQO
Dated: April 10, 2017
Received: April 11, 2017

Dear Nancy Nadler:

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 regulation (21 CFR Part 801), 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,


Kellie B. Kelm -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

Indications for Use

510(k) Number (if known)

k171083

Device Name

iChem®VELOCITY™ Automated Urine Chemistry System

Indications for Use (Describe)

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 iChemVELOCITY 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 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 iChemVELOCITY are intended for clinical laboratory and in vitro diagnostic use only.

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 for
iChem®VELOCITY™ Automated Urine Chemistry System – CGM
Design Change**

510(k) Owner / Submitter Information

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Date Submitted: April 10, 2017

Device Information

Trade Name: iChem® VELOCITY™ Automated Urine Chemistry System
 Common Name: Urine Chemistry Analyzer

Table 1: Regulatory Information

Classification Name	Product Code	Device Class	Regulation Number
Urinary glucose (non-quantitative) test system	JIL	II	21 CFR§862.1340
Occult blood test	JIO	II	21 CFR§864.6550
Urinary urobilinogen (non-quantitative) test system	CDM	I	21 CFR§862.1785
Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	I	21 CFR§862.1115
Ketones (non-quantitative test system)	JIN	I	21 CFR§862.1435
Urinary protein or albumin (non-quantitative) test system	JIR	I	21 CFR§862.1645
Nitrite (non-quantitative) test system	JMT	I	21 CFR§862.1510
Leukocyte peroxidase test	LJX	I	21 CFR§864.7675
Urinary pH (non-quantitative) test system	CEN	I	21 CFR§862.1550
Refractometer for Clinical Use	JRE	I	21 CFR§862.2800
Ascorbic Acid Test System	JMA	I	21 CFR§862.1095
Automated Urinalysis System	KQO	I	21 CFR§862.2900

Predicate Device Information

Candidate	Predicate	Manufacturer	510(k) No.	Date Cleared
iChemVELOCITY with re-designed CGM	iChemVELOCITY	Iris Diagnostics, a Division of Iris International Inc	K101852	03/23/2011

Device Description

The iChemVELOCITY is an automated urine chemistry system performing measurements of defined physical and chemical constituents in urine. The system utilizes iChemVELOCITY urine chemistry test strips which are read in the Strip Reader Module (SRM) by measuring light reflectance, in addition the iChemVELOCITY measures color and clarity using light transmittance through Color/Clarity Module (CCM) and specific gravity using refractive index through Specific Gravity Module (SGM).

The subject of this submission is a design change to the Color/Clarity Module (CCM) of the Color/Clarity/Specific Gravity Module (CGM) subassembly of the iChemVELOCITY. The CCM measures the color and clarity of a urine sample using transmitted and scattered light, incident on a color sensor. An algorithm then converts the output of the different channels of the sensor into semi-quantitative colors. The CCM is being changed to replace end-of-life components (color sensor and scatter light source) and update the color detection algorithm.

Intended Use/Indications 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 iChemVELOCITY 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.

These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function.

iChemVELOCITY strips are intended for use only with the iChemVELOCITY analyzer. In particular, they are not intended for visual reading. The iChemVELOCITY is not intended to be used as a Point of Care (POC) analyzer.

Tests performed using the iChemVELOCITY are intended for clinical laboratory and in vitro diagnostic use only.

Comparison to Predicate

The design change applied to the CCM is to replace the color sensor Taos TCS230 with Taos TCS3200 color sensor, along with the scatter LED due to end-of-life of the components. These components were chosen because of their similar characteristics to the components they replace. In addition to the electronic components, new firmware has been written and installed on the CCM’s microprocessor to control the new components and to update the CCM algorithm.

Color and clarity result categories are not changed with this design change, and the change is fit and functionally compatible with the subassembly as cleared in K101852. The CCM change is intended to provide a substantially equivalent subassembly with equivalent output to the original design as cleared in K101852.

Similarities and Differences between iChemVELOCITY as cleared in K101872 and the iChemVELOCITY with the redesigned CCM are shown in the table below.

Table 2: Comparison Between Proposed Device and Predicate Device

	iChemVELOCITY Analyzer K101852 (cleared on 3/23/2011)	Proposed Device iChemVELOCITY with Redesigned CCM
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 iChemVELOCITY 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	Same

	iChemVELOCITY Analyzer K101852 (cleared on 3/23/2011)	Proposed Device iChemVELOCITY with Redesigned CCM
	<p>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 iChemVELOCITY is not intended to be used as a Point of Care (POC) analyzer.</p> <p>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 iChemVELOCITY are intended for clinical laboratory and in vitro diagnostic use only.</p>	
Specimen analyzed	Urine collected in cup or other container, and transferred to a tube for sampling onto iChemVELOCITY test strips.	Same
Method of Operation	<p>Color change on the pads of the iChemVELOCITY strips are analyzed for percent reflectance and converted to results through an algorithm</p> <p>Urine color and clarity are obtained by measuring absorbance or scattering of white light through a flowcell. Intensities of RGB wavelengths are measured with a solid-state photodetector array.</p> <p>Specific gravity is measured by determining the refractive index of the specimen</p>	Same
Energy Source	AC power is converted to DC by an internal switching mode power supply	Same

	iChemVELOCITY Analyzer K101852 (cleared on 3/23/2011)	Proposed Device iChemVELOCITY with Redesigned CCM
Color Sensor	Taos TCS230	Taos TCS3200 Due to an obsolescence of the sensor
Scatter LED	Luxeonstar/Lumileds LXHL-LW3C	Luxeonstar/Lumileds SR-01-WC100
Microcontroller	PIC 18F25	Same
Board communications	UART	Same
Firmware	The CCM measures the light intensity in RGB channels. Then it corrects each channel using iChemVELOCITY wash solution as a reference source. The compensated RGB data is converted to project in 2 dimensional HSL color plane	Same method for the HSL color space, however boundaries for color bins were modified and an Ohta Color plane was added to refine color measurements along the boundaries of the HSL calculations.
Result format	Semi-quantitative results are presented for color and clarity. Specifically: Color – Red, Blue, Amber, Yellow, Straw, and Colorless Clarity – Turbid, Cloudy, Slightly Cloudy, and Clear	Same

Substantial Equivalence Conclusion

In order to demonstrate substantially equivalent performance of the proposed device to the predicate device for this design change, verification studies were designed and performed to ensure that the fit of the CCM in the iChemVELOCITY remained unchanged, and that the function of the CCM produced equivalent results to the predicate design. All testing successfully passed the acceptance criteria, and the test results demonstrated equivalence to the predicate.

In addition, no new hazards were introduced with the implementation of this change and therefore safety associated with the operation of this device remains unchanged.

In summary, the iChemVELOCITY with the redesigned CCM is substantially equivalent to the predicate device in regard to safety, effectiveness, and performance characteristics.

Summary of Performance Data

This design change is transparent to the user and does not alter any performance claims of the device. Various tests were conducted on the redesigned CCM to verify that fit and function of the subassembly did not impact the user experience or the performance characteristics of the iChemVELOCITY system. Verification studies were designed based on the risk analysis to verify that the proposed design performed better or equivalently to the predicate.

Performance testing of the iChemVELOCITY with the redesigned CCM was conducted to ensure that the system as a whole demonstrates equivalent performance to the predicate design. This testing included:

- Method Comparison
- Precision

Performance Test Summary

Table 3: Method Comparison Results Summary

		Comparator					
		Blue	Red	Amber	Yellow	Straw	Colorless
Redesigned CCM	Blue						18
	Red				3	18	
	Amber			5	18		
	Yellow		11	61	9		
	Straw		13				
	Colorless	18	12				
		Colorless	Straw	Yellow	Amber	Red	Blue
Exact match:		100.0%	36%	92%	60.0%	100.0%	100.0%
± 1 Block:		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

		Comparator			
		Turbid	Cloudy	Slightly Cloudy	Clear
Redesigned CCM	Turbid				32
	Cloudy		1	22	1
	Slightly Cloudy		7	13	
	Clear	87	16	1	
		Clear	Slightly Cloudy	Cloudy	Turbid
Exact match:		100.0%	29.2%	61.1%	97.0%
± 1 Block:		100.0%	100.0%	97.2%	100.0%

Table 4: Precision Results Summary

Color/Clarity	Test level	Number			% Exact agreement	% ± 1 block agreement
		Total	Exact agree	± 1 block agree		
Color	Colorless	240	240	240	100%	100%
	Straw	240	238	240	99.2%	100%
	Yellow	240	240	240	100%	100%
	Amber	240	240	240	100%	100%
	Red	240	237	239	98.8%	99.6%
	Blue	240	240	240	100%	100%
Clarity	Clear	240	240	240	100%	100%
	Slightly Cloudy	240	228	240	95.0%	100%
	Cloudy	240	240	240	100%	100%
	Turbid	240	240	240	100%	100%

Conclusion

Testing results verified that the iChemVELOCITY with the redesigned CCM produced results within the performance characteristics of the device and did not negatively impact the user experience.

The data presented in this Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution.

The testing results confirmed that the redesigned CCM was fit, functionally compatible and equivalent to the original CCM.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.