July 2, 2021

Beckman Coulter, Inc.
Marisa Pugliese
Staff Regulatory Affairs Specialist
11800 SW 147th Avenue
Miami, Florida 33196

Re: K210127
Trade/Device Name: iQ200 System, iChemVELOCITY Automated Urine Chemistry System
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated Cell Counter
Regulatory Class: Class II
Product Code: LKM, KQO, GKL, JIL
Dated: January 15, 2021
Received: January 19, 2021

Dear Marisa Pugliese:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lea Carrington
Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210127

Device Name
iQ200 System
iChemVELOCITY Automated Urine Chemistry System

Indications for Use *(Describe)*

iQ200 System:
The iQ200 automated urine microscopy system is an in vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ200 analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

iChemVELOCITY Automated Urine Chemistry System:
The iChemVELOCITY automated urine chemistry system is an in vitro diagnostic device used to automate the urine chemistry analysis profile using iChemVELOCITY Urine Chemistry Strips. The iChemVELOCITY can be used as a stand-alone system, as well as in an iQ200 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 nitrite, 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 use and in vitro diagnostics 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 Special 510(k) of the iQ200 System and iChemVELOCITY Automated Urine Chemistry

510(k) Owner / Submitter Information

Company Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 380-3002
Fax #: (786) 639-3002
Contact Person: Marisa Pugliese
Email Address: mpugliese@beckman.com

Date Submitted:

January 15, 2021

Device Information:

Trade Name: iQ200 System
Classification: Class II
Classification Name: Automated Cell Counter per 21 CFR 864.5200
Product Code: LKM; KQO; GKL
Panel: Hematology

Trade Name: iChemVELOCITY Automated Urine Chemistry
Classification: Class I
Classification Name: Automated Urinalysis System, per 21 CFR 862.2900
Product Code: JIL
Subsequent Product Codes: CDM, CEN, JIN, JIO, JIR, JJB, JMA, JMT, JRE, KQO, LJX
Panel: Clinical Chemistry

Predicate Device Information:

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
iQ200 System	K022774	Oct. 21, 2002	Class II Class I	864.5200 862.2900	LKM KQO
iQ200 Urine Analyzer Body Fluids Module	K050235	Mar. 23, 2005	Class II	864.5200	GKL
iQ200 System with Lamina Cradle	K093861	Feb. 05, 2010	Class II Class I	864.5200 862.2900	LKM KQO
iQ200 Urine Analyzer Body Fluids Module (The addition of Synovial Fluid)	K091539	Aug. 31, 2010	Class II	864.5200	GKL
iChemVELOCITY Automated Urine Chemistry	K101852	Mar. 23, 2011	Class I	862.2900	KQO

iChemVELOCITY Automated Urine Chemistry	K171083	May 12, 2017	Class II Class I	862.1340 862.2900	JIL KQO

iQ200 System and iChemVELOCITY Urinalysis System

This CBE (Changes Being Effected) 510(k) submission is due to system software changes to be implemented as part of the corrective action for a field action initiated by BEC in Z-0913-2020 and Z-0914-2020 reported on April 15, 2020.

The software change is for the iQ200 System and iChemVELOCITY Automated Urine Chemistry systems with its Analysis Processor User Interface or APUI software version 7.2 for Windows7 and XP Operating Systems.

Device Description:

The iQ200 System auto-identifies and processes specimens in 10-position racks by mixing, sampling, and analyzing automatically. The iQ200 Series Automated Urine Microscopy system presents a specimen sandwiched between enveloping layers of lamina to a microscope coupled to a CCD (charge coupling device) video camera. This lamination positions the specimen exactly within the depth of focus and field of view of the objective lens of the microscope. The iQ200 System provides automatic sample handling for automated intelligent microscopy and automatic analyte classification for improved data reporting, presentation and management. Specimens are aspirated by an autosampler rather than poured manually. Individual particle images are isolated within each frame. The Auto-Particle Recognition (APR) software, uses size, shape, contrast and texture features to classify each image into one of 12 categories: RBCs, WBCs, WBC Clumps, Hyaline Casts, Unclassified Casts, Squamous Epithelial Cells, Non-squamous Epithelial Cells, Bacteria, Yeast, Crystals, Mucus and Sperm. Additionally, 27 predefined sub-classifications are available for identifying specific types of casts, crystals, non-squamous epithelial, dysmorphic, and others. Particle concentration is calculated using the number of particles images and the volume analyzed. User-defined release criteria are checked and results are sent to an operator review screen or directly uploaded to the LIS based on these criteria. Specimen results can be edited, imported, and exported.

The iQ Body Fluids Module is a software program that runs on the iQ Series Systems and automates body fluid sample handling, capturing particle images in a manner similar to that of the urinalysis application. The iQ200 Series System uses a CCD camera to capture images from each sample.

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. The device is a fully automated, computer-controlled urine chemistry analyzer intended for use only with iChemVELOCITY Urine 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. 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.

The primary function of the iQ200 and iChemVELOCITY analyzers is to process samples and provide results to the workstation. The primary functions of the workstation are: user interface, system control, results processing, data storage, and external communications. The analyzers run embedded code on micro controllers and the workstation software runs Microsoft Windows 7 or Windows XP Operating System (OS). The workstation can be connected to:

- A printer for creating reports
- A Laboratory Information System (LIS) for receiving test orders and releasing results.

Design Change Description

The modification prompting a new submission is an update to the iQ200 and iChemVELOCITY APUI software included in version 7.2 (for Windows 7 and XP Operating System). It contains the following changes:

If a duplicate specimen is detected by the APUI software one of the two flags will be generated:

Flag 1: If duplicate specimen ID is found with the same Medical Record Number, then software will flag the result as "DUPLICATE SPECIMEN ID (SAME MEDICAL RECORD NUMBER)".

Flag 2: If the duplicate specimen ID found has a different Medical Record Number, then software will flag the result as "DUPLICATE SPECIMENT ID (DIFFERENT MEDICAL RECORD NUMBER)".

If either of these flags appear, the specimen result will be held until the operator reviews the result. The operator will follow labelling instructions to resolve the flag.

APUI software uses a time window to determine whether a duplicate specimen is presented to the analyzer. This time window can be configured by the user. Allowable values range from 12 to 72 hours. The default value for the time window is 12 hours.

For example, if the user configures the time window as 24 hours, then, APUI will flag a specimen as duplicate, if it's ran within 24 hours of another specimen with the same identifier.

The upper limit for the review time frame is consistent with the shelf life of preservative tubes used with urine sample which is 72 hours. Based on this fact, an operator using preservative tubes can run the chemistry and continue on to the microscopy at a later time while still maintaining the urine sample integrity. When a specimen is presented and processed, the

system will scan the database for specimens with the same identifier. Beyond the 72 hours timeframe, a specimen ID can be re-used and the system will not flag for a duplicate ID. The lower limit for the review timeframe is designated to align with the possibility that high volume laboratories can re-use the specimen ID more frequently based on the laboratory SOPs. Section 10 will provide further details on software workflow.

Cybersecurity Update

Included as part of this software modification is an update to the Windows XP Operating System (OS) cybersecurity to address Bluekeep and WannaCry vulnerabilities.

The following Cybersecurity tests were done on Windows XP Operating System.

1. Vulnerability Assessment scan was successfully performed.
2. A penetration test was successfully done by Beckman Coulter. Based on the test results, XP Operating System was patched for the most common Bluekeep and WannaCry viruses.
    - Bluekeep is a security vulnerability that was discovered in Microsoft's Remote Desktop Protocol implementation which allows for the possibility of remote code execution.
    - WannaCry is a ransomware attack that targeted Windows XP computers by encrypting data and demanding ransom payment in the Bitcoin cryptocurrency.

A source code review was successfully done for both Window XP and Window 7 by Beckman Coulter. Vulnerabilities reported by this tool have been triaged.

Reports for the above scans are available upon request.

Windows 7 Operating System does not have Bluekeep vulnerability since all the Remote Desktop Protocol ports are closed by the OS image.

Windows 7 Operating System is not susceptible to WannaCry ransomware attack since the OS image has a firewall that cannot be disabled, and communication ports are closed to external connections.

iQ200 and iChemVelocity analyzers have a layered approach for cybersecurity. These systems are isolated from outside networks. In addition, both Operating Systems has access controls for users to prevent unauthorized use.

Intended Use/Indications for Use:

iQ200 System (K022774) Intended Use:

The iQ200 automated urine microscopy system is an in vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ200 analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for

auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

Note: There is no change to the system's intended use as a result of this software design change.

iQ Body Fluids Module (K050235) Intended Use:

The iQ Body Fluids Module is an in-vitro diagnostic device used by a trained human observer to examine and count red blood cells and other nucleated cells in cerebrospinal fluid, and serous fluids.

Note: There is no change to the intended use as a result of this software design change.

iQ200 System with Lamina Cradle (K093861) Intended Use:

The iQ Lamina Cradle is a new accessory to be used with the iQ200 Series of Urine Microscopy Analyzers (K022774). The iQ 200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ 200 Analyzer can be used as a stand-alone unit, or the results from the iQ 200 Analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

Note: There is no change to the system's intended use as a result of this software design change.

iQ200 Urine Analyzer Body Fluids Module (The addition of Synovial Fluid)

The iQ200 Urine Analyzer Body Fluids Module for use with synovial fluid is an additional use for the iQ200 Urine Analyzer (K022774). The iQ200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by an appropriately trained laboratory user to examine and count red blood cells and nucleated cells in cerebrospinal fluid, serous fluids and synovial fluid. This module is a capability added to the iQ0200 Urine Analyzer.

Note: There is no change to the system's intended use as a result of this software design change.

iChemVELOCITY Automated Urine Chemistry System (K101852 & K171083) Intended Use:

The iChemVELOCITY automated urine chemistry system is an in vitro diagnostic device used to automate the urine chemistry analysis profile using iChemVELOCITY Urine Chemistry Strips. The iChemVELOCITY can be used as a stand-alone system, as well as in an iQ200 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 nitrite, 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.

Note: There is no change to the system's intended use as a result of this software design change.

Comparison to Predicate:

The design changes applied to the iQ200 System and iChemVELOCITY analyzers serve as additional mitigations to new risk control measures to the potential failure mode identified in the root cause analysis of the field action that initiated these changes.

These software design changes do not impact the intended use or performance claims of the iQ200 Automated Urine Microscopy and iChemVELOCITY Automated Urine Chemistry analyzers.

Device Comparison Table:

Table 1 - iQ200 System

Performance and Characterization	IQ200 System – K022774 (Cleared Oct. 21, 2002), K050235 (Cleared Mar. 23, 2005), K093861 (Cleared Feb. 05, 2010), K091539 (Cleared Aug. 31, 2010)	Proposed Device
Intended Use	The iQ200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ200 Analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist. The iQ200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by an appropriately trained laboratory user to examine and count red blood cells and nucleated cells in cerebrospinal fluid, serous fluids and synovial fluid.	No change

Performance and Characterization	IQ200 System – K022774 (Cleared Oct. 21, 2002), K050235 (Cleared Mar. 23, 2005), K093861 (Cleared Feb. 05, 2010), K091539 (Cleared Aug. 31, 2010)	Proposed Device
Specimen analyzed	iQ200 System: Urine collected in a cup or other container and transferred to a tube for analysis. iQ Body Fluids and Synovial: Hyaluronidase is added to the specimen, mixed and incubated. Two aliquots from each body fluid specimen are prepared. One aliquot is diluted in normal saline to provide a concentration in the linear range of the instrument. The second aliquot is treated with a lysing reagent to allow unambiguous identification of WBC and other nucleated cells by eliminating RBC confusion. Particle images are captured and saved electronically as the sample flows past a microscope objective at a high speed, electronically concentrating particles. Particle images are then ordered by size into assigned categories on a video display.	No change
Mechanism for introducing specimen	Specimen automatically mixed and withdrawn from a tube into the analytical system.	No change
Mechanism for presenting individual formed element images to microscope objective	Individual elements in liquid suspension automatically selected and imaged by a microscope objective as they move through a flow cell.	No change
Presentation of images for viewing	Individual formed elements are presented on a video monitor on a separate microcomputer in machine-ordered and counted groups by analyte type or by like size.	No change

Performance and Characterization	IQ200 System – K022774 (Cleared Oct. 21, 2002), K050235 (Cleared Mar. 23, 2005), K093861 (Cleared Feb. 05, 2010), K091539 (Cleared Aug. 31, 2010)	Proposed Device
Features used to distinguish among formed element types	Differential staining separates cells and organisms. Casts are discerned based on size and density. Crystals are determined based on size, shape, and refractive intensity.	No change
Microscopic sediment and chemistry results are saved in computer memory prior to review, and release by operator.	Result data are stored on the workstation for later review, independent of analysis.	No change
Presentation of images to skilled, competent observer	Formed elements in the flow cells are viewed through a microscope by a video camera. Images are captured and electronically presented to a skilled, competent observer for interpretation on a video monitor.	No change
Image montage organization and comprehension	Formed elements are sorted into groups of analytes determined by machine classification. All groups are displayed in a single montage for "at a glance" visual confirmation. Individual groups can also be viewed independently.	No change
Reclassification of formed element images by a competent observer	Formed element images displayed can be reclassified by selecting a "button" for the correct analyte type and then selecting individual images to be renamed.	No change

Performance and Characterization	IQ200 System – K022774 (Cleared Oct. 21, 2002), K050235 (Cleared Mar. 23, 2005), K093861 (Cleared Feb. 05, 2010), K091539 (Cleared Aug. 31, 2010)	Proposed Device
Results are observed and expressed	Scanning is accomplished "at a glance" of a montage on a video monitor displaying all formed element images detected. Final counts are based on machine classification of analyte images or those of a competent observer if the specimen is flagged for human review or the operator chooses to provide analyte identifications.	No change
Throughput	• 101 urine sample/hour • 70 urine sample/hour • 40 urine sample/hour	No Change
Software	APUI Software version 6.2	APUI Software version 7.2 (for Windows7 & XP OS)

Table 2 - iChemVELOCITY Automated Urine Chemistry

	iChemVELOCITY Analyzer K101852 (cleared on 3/23/2011) and K171083 (cleared on 05/12/2017)	**Proposed Device**
Intended Use	The iChemVELOCITY automated urine chemistry system is an in vitro diagnostic device used to automate the urine chemistry analysis profile using iChemVELOCITY 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.	No change
Specimen analyzed	Urine collected in cup or other container and transferred to a tube for sampling onto iChemVELOCITY test strips.	No change
Method of Operation	Color change on the pads of the iChemVELOCITY strips are analyzed for percent reflectance and converted to results through an algorithm 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. Specific gravity is measured by determining the refractive index of the specimen	No change
Energy Source	AC power is converted to DC by an internal switching mode power supply	No change

	iChemVELOCITY Analyzer K101852 (cleared on 3/23/2011) and K171083 (cleared on 05/12/2017)	Proposed Device
Color Sensor	Taos TCS230	No change
Scatter LED	Luxeonstar/Lumileds SR-01-WC100	No change
Microcontroller	PIC 18F25	No change
Board communications	Universal Asynchronous Receiver/Transmitter (UART)	No change
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. Method for the HSL color space is boundaries for color bins modified and an Ohta Color plane was added to refine color measurements along the boundaries of the HSL calculations.	No change
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	No change
Throughput	210 urine sample/hour	No change
Software	APUI Software version 6.2	APUI Software version 7.2 (for Windows7 & XP OS)

Summary of Performance Testing:

To demonstrate substantial equivalence (SE), the following design performance verification analysis was performed and evaluated:

1. Method Comparison

Design Control Activities

The development and design verification and validation of the device software modification has been performed under design controls. The design control activities were based on risk analysis, and acceptance criteria were set to maintain the efficiency and safety of the device. Design testing included: software verification, system performance verification, validation, human factors, and installation.

Substantial Equivalence Conclusion to Demonstrate Safety, Effectiveness & Equivalent Performance to Predicate:

The updates to the iQ200 System and iChemVELOCITY analyzers that are the subject of this submission, do not change the intended use, nor add or delete a contraindication for the device. The changes do not alter the device control mechanism, operating principle, energy type, environmental specification, ergonomics of the user interface, dimensional specifications, nor packaging.

The device does not have expiration dating nor is it subject to sterilization.

In summary, it can be concluded that the updated iQ200 System and iChemVELOCITY analyzers, as described in this submission is substantially equivalent in terms of safety and effectiveness to the predicate device.

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.