510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k060280

B. Purpose for Submission:

Modified 510(k): The sponsor wishes to establish clear ownership of their earlier cleared test system which will now be marketed under a new name. Additionally, the analyzer software was modified since the initial clearance of the product.

C. Manufacturer and Instrument Name:

Iris Diagnostics facility in Marburg, Germany, iChem 100 Urine Chemistry Analyzer

(IRIS is an abbreviation for International Remote Imaging Systems.)

D. Type of Test(s) Performed:

Qualitative and Semi-quantitative urine chemistry assays

E. System Description

1. Device Description:

   This is a semi-automated benchtop instrument, intended exclusively for use with the sponsors earlier cleared test strips (k030600). Components include a keyboard, transport mechanism, display screen, printer, and barcode reader.

   Test strips are manually dipped into the urine sample and placed on the instrument transport belt. The strip is transported into the instrument where readings of each chemistry are taken at timed intervals. Readings are converted to concentrations which are displayed to the operator. There are also options to print results or to transmit them to a Laboratory Information System.

2. Principles of Operation:

   The technology utilized in the instrument is reflectance spectroscopy. The reflectance densitometer reads at three wavelengths; 450, 530, and 625 nm. Instead of using a photodiode detector to measure the reflected light, the instrument utilizes a complementary metal oxide semiconductor (CMOS) image sensor. This technology is

well established and is the same as the sponsor's earlier cleared instrument.

3. Modes of Operation:

   The instrument allows both batch and stat modes.

4. Specimen Identification:

   Specimens are identified by a barcode reader or by manual input via the keyboard. A work list can also be created by the operator.

5. Specimen Sampling and Handling:

   The iChem reagent strip is manually dipped into a urine specimen then placed on the instrument transport belt. All steps that follow are automatically controlled by the instrument's software.

6. Calibration:

   No external calibration strips or procedures are required. Prior to each measurement the device is calibrated using a one-point optics alignment calibration. If readings fall outside of acceptable limits, a secondary standard is moved into place to perform a two-point calibration. The approach to calibration is appropriate for the CMOS image sensor technology.

7. Quality Control (QC):

   A control file may be set up by the operator to record the lot and expiration of the control material, and to establish the frequency for running controls. The software also allows manual microscopic examination results to be entered into the system.

   Commercially available control materials (negative and known positive concentrations) are recommended for use according to local, state, and federal regulatory guidelines. Specific controls are not identified.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes X__ or No _____

   The following sections are presented in the submission, and they appear adequate:

Level of Concern –The sponsor has classified their device as a Moderate Level of Concern.

Software Description- An overview of the features controlled by the software and the software operating environment is present.

Hazard Analysis- A summary of the Failure Mode and Effects Analysis activity is presented. It lists hardware and software hazards, severity assessments, and mitigations. It identifies the cause(s) of hazards, methods of control (e.g., alarm, hardware design), corrective measures taken, including an explanation of the aspects of the device design/requirements, that eliminate, reduce, or warn of a hazardous event, and verification that the method of control was implemented correctly.

Software Requirements Specification (SRS) - A document listing functional requirements for the software, e.g., interface, performance, or functional needs is provided.

Architecture Design Chart- A design specification document is provided.

Traceability Analysis- Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing is provided.

Software Development Environment Description- A summary of the software development life cycle and the processes that are in place to manage the various life cycle activities is provided, e.g., changes or adjustments to software after released into market. Additionally, an annotated list of control documents generated during the development process is present. It includes a summary of the configuration management and maintenance activities. (The waterfall process model of development was used.)

Verification and Validation Documentation- A description of V&V activities at the unit, integration, and system level are present. System level test protocols, including pass/fail criteria, and test results are also provided.

Revision Level History - The sponsor has provided the Revision history log, including release version number and date.

Unresolved Anomalies - The sponsor indicates there are no known unresolved anomalies at the time of this submission. Therefore, a list of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors is not needed.

F. Regulatory Information:

1. Regulation section:
      Class II:
      21CFR §862.1340 - Urinary glucose (nonquantitative) test system
      21CFR §864.6550 - Occult blood test

Class I:
21 CFR §862.1095 - Ascorbic acid test system
21 CFR §862.1115 - Urinary bilirubin and its conjugates (nonquantitative) test system.
21 CFR §862.1435 - Ketones (nonquantitative) test system
21 CFR §862.1510 - Nitrite (nonquantitative) test system
21 CFR §862.1550 - Urinary pH (nonquantitative) test system
21 CFR §862.1645 - Urinary protein or albumin (nonquantitative) test system
21 CFR §862.1785 - Urinary urobilinogen (nonquantitative) test system
21 CFR §862.2300 - Colorimeter, photometer, or spectrophotometer for clinical use
21 CFR §864.7675 - Leukocyte peroxidase test
21CFR §862.2900 - Automated urinalysis system

2. Classification:

Class II (blood and glucose) and the remainder are Class I   (The class I analyzer is subject to review because Class II analytes are run on it. Class I analytes are reviewed because they are part of a device which includes class II devices.)

3. Product code:

Class II: JIL, JIO

Class I: JMA, JJB, JIN, JMT, CEN, JIR, CDM, JJQ, LJX, KQO

4. Panel:

75 (Chemistry)

G. Intended Use:

1. Indication(s) for use:

The iChem100 Urine Chemistry Analyzer (iChem100) is a semi-automated benchtop urine chemistry analyzer intended for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocyte esterase, ascorbic acid, and color. The iChem100 is intended for use only with iChem 10 SG Urine Chemistry Strips provided by Iris Diagnostics and is intended for use exclusively by healthcare professionals.

These measurements are useful in the evaluation of renal, urinary, and metabolic disorders.

2. Special conditions for use statement(s):

For professional use.

H. Substantial Equivalence Information:

1. Predicate device name(s):

   AUTION JET AJ-4270, IRIS Diagnostics

2. Predicate 510(k) number(s):

   k030600

3. Comparison with predicate:
   Both devices measure various chemistry parameters in urine, are semi-automated analyzers, and utilize the same test methodology.

   The site where the instruments are manufactured are different, however both are manufactured by IRIS Diagnostics, International.

I. Standard/Guidance Document Referenced (if applicable):

The sponsor references the following standards:

EN 51010A-1 Safety requirements for electrical equipment, Part 1, General requirements.

CAN/CSA-C22.2, No. 1010.1, Safety requirements for electrical equipment, Part 1, General requirements.

J. Performance Characteristics):

1. Analytical performance: To demonstrate performance of the iChem analyzer the sponsor presents data from two types of studies, as appropriate. (Not all studies are done for each analyte.)

   a. *Accuracy:*

   Results from the iChem100 were compared to those from a commercially available system, the AUTION JET AJ-4270 test system. Ascorbic Acid was compared to the UrinQuic device.

   Testing was performed by skilled personnel at IRIS. Clinical Urine samples for the study were obtained from a local medical center. The samples include both normal and abnormal levels of urine analytes.

   Results obtained in these correlation studies are presented in block tables according to the

ranges reported by the individual systems. Additionally, values obtained from all urine samples were referred to as either negative (normal) or positive (abnormal) findings. These data are presented in 2X2 tables for comparison of the two assay methods.

Glucose Correlation Study: Categorized by Reporting Ranges (mg/dL)

		Arkray Result					
		Neg.	@ 30/50	@ 70/100	@ 150/200	@ 300/500	@ > 1000	Total
iChem Result	Neg.	156	0	0	0	0	0	156
	@ 50	2	5	5	0	0	0	12
	@ 150	0	0	1	3	4	3	11
	@ 500	0	0	0	0	1	5	6
	@ > 1000	0	0	0	0	0	3	3
	Total	158	5	6	3	5	11	188

Glucose Correlation Study: Categorized by Negative/Positive Findings

	Arkray Negative	Arkray Positive	Total
iChem Negative	156	0	156
iChem Positive	2	30	32
Total	158	30	188

Blood Correlation Study: Categorized by Reporting Ranges (mg/dL)

		Arkray Result					
		0	@ 0.03	@ 0.06/0.1	@ 0.2/0.5	@ 1	Total
iChem Results	0	147	1	2	0	0	150
	@ 0.03	4	12	3	1	0	20
	@ 0.2	0	1	0	3	2	6
	@ 1.0	1	0	0	2	9	12
	Total	152	14	5	6	11	188

Blood Correlation Study: Categorized by Negative/Positive Findings

	Arkray Negative	Arkray Positive	Total
iChem Negative	147	3	150
iChem Positive	5	33	38
Total	152	36	188

The following analytes were tested using both spiked samples (compared to expected spiked

value) and clinical samples compared to results from a predicate device:

Ascorbic Acid

		Spiked Concentration (mg/dL)				
		0	10	20	30	40
	40			3	25	40
	20			60	38	23
iChem 100	Neg	63	63			

		Predicate Device (mg/dL)		
		Neg	20	40
iChem 100	40		3	1
	20	2	9	
	Neg	89		

Bilirubin

		Spiked Concentration (mg/dL)					
		0	0.8	1	1.5	2	4
iChem 100	4						9
	2				22	53	53
	1				30	7	1
	Neg	63	63	63	27	3	

		Predicate Device (mg/dl)				
		0	0.5-1.0	2.0	6.0-10.0	>10.0
iChem 100	4	1		3		1
	2	8	3	14		
	1	6	7			
	Neg	141	2	2		

Ketones

		Spiked Concentration (mg/dL)					
		0	20	25	30	100	300
iChem 100	300					2	55
	100					59	2
	25		42	53	48		
	Neg	54					

iChem 100		Predicate Device (mg/dL)			
		0	5-60	80-100	>150
	300				
	100				
	25	4	16		
	Neg	167	1		

Leukocytes

iChem 100		Spiked Concentration (WBC/µL)					
		0	15	25	50	75	500
	500			11	9	10	57
	75		6	29	24	22	6
	25		57	26	32	27	
	Neg	63		1		4	

iChem 100		Predicate Device (WBC/µL)				
		0	25	75	250	500
	500			3	5	11
	75		1			1
	25	17	3	2	1	
	Neg	142		2		

Nitrite

iChem 100		Spiked Concentration (mg/dL)			
		0	0.03	0.05	0.08
	Pos		32	44	59
	Neg	57	32	19	4

iChem 100		Predicate Device (mg/dL)			
		0	0.03	0.05	0.08
	Pos	2	31		
	Neg	154	1		

pH

iChem 100		Spiked Concentration (pH meter)				
		5	6	7	8	9
	5.0	10				
	6.0		2			
	7.0		8			
	8.0			10		
	9.0				10	10

iChem 100		Predicate Device (pH)				
		5.0-5.5	6.0-6.5	7.0-7.5	8.0-8.5	9.0
	9.0			1		2
	8.0			8		
	7.0		15	5		
	6.0	10	34	1		
	5.0	87	25			

Protein

iChem 100		Spiked Concentration (mg/dL)					
		0	15	30	50	100	500
	500						42
	100				14	42	
	30		5	42	28		
	Neg	42	37				

iChem 100		Predicate Device (mg/dL)			
		0	10-70	100-200	300-600
	500				3
	100		2	15	2
	30	13	37	1	
	Neg	112	2	1	

Specific Gravity

iChem 100		Spiked Concentration (refractometer)							
		1.000	1.005	1.010	1.015	1.020	1.025	1.030	1.035
	1.000	10							
	1.005		10	8					
	1.010			2	2				
	1.015				8	2			
	1.020					8	1		
	1.025						9	3	
	1.030							7	10
	1.035								

iChem 100		Predicate Device (Sp. Grav.)							
		1.000	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**	**>1.030**
	1.035							3	1
	1.030						1	9	9
	1.025		1			3	5	13	9
	1.020					8	14	3	5
	1.015				1	16	8	1	
	1.010			1	12	12			
	1.005		15	8	9	5	2		
	1.000		3						

Urobilinogen

iChem 100		Spiked Concentration (mg/dL)						
		0	**1**	**2**	**3**	**4**	**8**	**12**
	12							
	8				57	56	57	58
	4		5	24	1	3		
	2		52	9		1		
	Neg	63	23	1				

iChem 100		Predicate Device (mg/dL)				
		0	**2-3**	**4-6**	**8-12**	**>12**
	12					1
	8	1	2	3	1	
	4		4			
	2	12	5			
	Neg	157	2			

Color

Since the predicate device and the subject device differ in the number of colors for reporting results (16 for the predicate and 10 for the subject device), the sponsor compared the color on the two devices in 629 clinical samples:

iChem 100	Predicate Device (color)							
	Colorless	Light Yellow	Yellow/Dark Yellow	Light Orange/Orange/Dark Orange	Light Red/Red/Dark Red	Light Brown/Brown/Dark Brown	Green	Violet/Blue
Black						1		
Green								
Brown								
Red Brown						1		
Red			18		6			
Orange			2	1		3		
Amber	4	2	111	2	11	8		
Yellow	52	72	305	4	1			
Straw	12	4	6					
Colorless			3					

b. Precision/Reproducibility:

Two levels of commercially available control (normal and abnormal concentrations of each analyte) were analyzed to estimate precision of the test system. Testing was performed in the sponsor's own laboratory by their employees.

To estimate total imprecision, 23 abnormal samples and 20 normal samples were run over a 13 day period. To estimate within-run imprecision 20 normal and 20 abnormal samples were analyzed in a single run. Testing was performed on the candidate device, and the candidate device prior to the software modifications. Testing was done in the sponsor's laboratory by trained laboratory technicians.

Total Precision, Candidate Device at Normal Levels

Analyte	Control Range	% Reflectance	Standard deviation	% CV	95% Confidence Interval for CV
Bilirubin	Neg	63.6	2.1	3.3	[2.6-4.7]
Urobilinogen	Norm	57.7	1.9	3.3	[2.6-4.7]
Ketones	Neg	57.9	2.3	4.0	[3.1-5.6]
Ascorbic Acid	20-40 mg/dL	56.2	1.2	2.1	[1.6-3.0]
Protein	Neg	61.9	1.2	1.9	[1.5-2.7]

Analyte	Control Range	% Reflectance	Standard deviation	% CV	95% Confidence Interval for CV
PH	5-9	66.6	1.0	1.5	[1.2-2.1]
Nitrite	Neg	65.1	2.1	3.3	[2.5-4.6]
Leukocyte	Neg	62.5	1.9	3.0	[2.4-4.3]
Specific Gravity	1.000-1.035	27.9	1.3	4.5	[3.6-6.6]
Blood	Neg	65.4	0.8	1.2	[0.9-1.7]
Glucose	Neg	78.9	1.4	1.8	[1.4-2.5]

Total Precision, Candidate Device at Abnormal Levels

Analyte	Control Range	% Reflectance	Standard deviation	% CV	95% Confidence Interval for CV
Bilirubin	1-4 mg/dL	28.5	2.5	8.8	[6.8-12.5]
Urobilinogen	2-12 mg/dL	38.2	1.9	5.0	[3.8-7.0]
Ketones	25-300 mg/dL	7.5	0.7	9.3	[7.2-13.3]
Ascorbic Acid	Neg	7.9	0.7	8.9	[6.8-12.6]
Protein	30 - ≥500 mg/dL	29.0	0.9	3.1	[2.4-4.4]
PH	5-9	39.8	1.3	3.3	[2.5-4.6]
Nitrite	Pos	46.4	1.5	3.2	[2.5-4.6]
Leukocyte	25-500 WBC's/uL	54.3	1.3	2.4	[1.8-3.4]
Specific Gravity	1.000-1.035	19.8	1.5	7.6	[5.8-10.8]
Blood	0.03-1 mg/dl	4.1	0.1	2.4	[1.9-3.4]
Glucose	50-≥1000/mg/dL	20.8	1.3	6.2	[4.8-8.9]

Within-Run Precision, Candidate Device at Normal Levels

Analyte	Control Range	% Reflectance	Standard deviation	% CV	95% Confidence Interval for CV
Bilirubin	Neg	65.1	1.7	2.6	[2.0-3.8]
Urobilinogen	Norm	59.9	1.4	2.3	[1.8-3.4]
Ketones	Neg	60.6	1.5	2.5	[1.9-3.6]
Ascorbic Acid	20-40	55.4	0.7	1.3	[1.0-1.8]

Analyte	Control Range	% Reflectance	Standard deviation	% CV	95% Confidence Interval for CV
	mg/dL				
Protein	Neg	60.7	0.4	0.66	[0.5-1.0]
PH	5-9	65.4	1.0	1.5	[1.2-2.2]
Nitrite	Neg	67.8	1.8	2.6	[2.0-3.9]
Leukocyte	Neg	64.8	1.2	1.8	[1.4-2.7]
Specific Gravity	1.000-1.035	26.1	0.8	3.1	[2.3-4.5]
Blood	Neg	65.0	0.6	0.9	[0.7-1.3]
Glucose	Neg	79.0	1.4	1.8	[1.3-2.6]

Within-Run Precision, Candidate Device at Abnormal Levels

Analyte	Control Range	% Reflectance	Standard deviation	% CV	95% Confidence Interval for CV
Bilirubin	1-4 mg/dL	30.5	1.7	5.6	[4.2-8.2]
Urobilinogen	2-12 mg/dL	40.2	1.8	4.5	[3.4-6.5]
Ketones	25-300 mg/dL	8.8	0.5	5.7	[4.3-8.3]
Ascorbic Acid	Neg	8.1	0.3	3.7	[2.8-5.4]
Protein	30 - ≥500 mg/dL	29.0	0.4	1.4	[1.0-2.0]
PH	5-9	38.6	1.2	3.1	[2.4-4.5]
Nitrite	Pos	47.9	1.2	2.5	[1.9-3.7]
Leukocyte	25-500 WBC's/uL	55.5	0.8	1.4	[1.1-2.1]
Specific Gravity	1.000-1.035	21.1	1.4	6.6	[5.0-9.7]
Blood	0.03—1 mg/dl	3.8	0.1	2.6	[2.0-3.8]
Glucose	50-≥1000/mg/dL	20.1	1.5	7.4	[5.7-10.9]

c. *Linearity/assay reportable range:*

Analyte free urine was fortified with glucose or hemoglobin to various concentrations spanning the reportable range of the assay. Results appear linear.

The discrete reporting levels for glucose are 0, 50, 150, 500, and ≥ 1000 mg/dL of glucose.
Glucose Linearity Study Results

Known Analyte Concentration (mg/dL)	Observed Result (mg/dL)
1500	≥ 1000
1000	≥ 1000
500	500
400	500
200	150
100	150
50	50
30	50
0	0

Discrete reporting levels for blood are 0, 0.03, 0.2, and 1.0 mg/dL hemoglobin.

Hemoglobin Linearity Study Results

Known Analyte Concentration (mg/dL)	Observed Result
1.0	1.0
0.9	1.0
0.5	1.0
0.1	0.2
0.03	0.03
0	0

See the method comparison section above for performance of spiked samples with the other analytes.

d. Carryover:

There are no apparent carryover issues with this test system/ instrument. Strips are unitized devices. They are manually dipped, with excess liquid being removed. Strips are then placed in a horizontal position for analysis. There is little chance for run over, and no problems were observed during studies.

e. Interfering Substances:

Because test strips have not been changed, and only minor modifications have been made to the instrument which should not affect performance, these studies were not repeated.

2. Other Supportive Instrument Performance Data Not Covered Above:

Instrument maintenance is minimal, i.e., wiping the outside of the instrument and transporter belt, and emptying the waste container.

K. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.