September 8, 2023

Randox Laboratories Limited
Karena Shaw
Regulatory Affairs Manager
55 Diamond Road
County Antrim, BT29 4QY
United Kingdom

Re: K230890
Trade/Device Name: ISE Electrodes
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium Test System
Regulatory Class: Class II
Product Code: CEM, CGZ, JGS
Dated: August 11, 2023
Received: August 11, 2023

Dear Karena Shaw:

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K230890

Device Name
ISE Electrodes

Indications for Use *(Describe)*
The ISE Electrodes on the RX Imola can be used for measurement of the electrolytes sodium, potassium and chloride in serum and urine and for use in diagnosis and treatment of electrolyte imbalance.

For 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)

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RANDOX

SPECIAL 510(k) SUMMARY
K230890

General Information

Name: Randox Laboratories Limited

Address: 55 Diamond Road, Crumlin,
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Telephone: +44 (0) 28 9442 2413
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Contact: Karena Shaw
E-mail: karena.shaw@randox.com

Device Identification

Proprietary Names: ISE Electrodes

Table 1: Candidate Device Regulatory Summary

Product Code	Regulation Name	Classification	Regulation Section	Panel
CEM	Electrode, Ion-Specific, Potassium	II	21 CFR 862.1600	Clinical Chemistry (75)
CGZ	Electrode, Ion-Specific, Chloride	II	21 CFR 862.1170	Clinical Chemistry (75)
JGS	Electrode, Ion-Specific, Sodium	II	21 CFR 862.1665	Clinical Chemistry (75)

Predicate Device:

Previously cleared unmodified device: RX imola (k052914)

RANDOX

DEVICE DESCRIPTION

RX imola is an automated clinical chemistry analyzer complete with dedicated analyzer software. Software functions of the analyzer include the facility to interact with a host computer for direct download of test method selection details for individual samples. A barcode system is used for the rapid identification of patient samples, reagents and QC samples.

In addition, the RX imola is fitted with an Ion Selective Electrode (ISE) module that operates in conjunction with specific electrodes for the quantitative in vitro diagnostic determination of Sodium, Potassium and Chloride in serum and urine.

INTENDED USE

The ISE Electrodes on the RX Imola can be used for measurement of the electrolytes sodium, potassium and chloride in serum and urine and for use in diagnosis and treatment of electrolyte imbalance.

For in vitro diagnostic use only.

DESCRIPTION OF MODIFICATION TO EXISTING DEVICE

Following discontinuation of the original ISE unit, the RX imola instruments purchased will now be fitted with a new ISE electrodes for Sodium, Potassium & Chlorides. RX imola instruments fitted with the new ISE electrodes will be identified by an alternate serial number prefix (7255).

The new ISE unit being implemented through this Special 510(k) was previously cleared under k131554 for our RX DAYTONA PLUS CHEMISTRY ANALYZER. The data included in this Special 510(k) summary is based on a comparison of the original ISE electrodes used in conjunction with RX imola (K052914) and the new ISE electrodes that will now be used with the RX imola.

COMPARISON WITH PREDICATE DEVICE

The following table describes the similarities and differences between

- ISE device originally cleared with the RX imola through K052914
- Candidate ISE device with the RX imola analyser

Table 2: Comparison with predicate device

Similarities

Parameter	RX imola Automated Analyzer With previous ISE unit (ORIGINALLY CLEARED DEVICE K052914)	RX imola Automated Analyzer With New ISE Unit (CANDIDATE DEVICE K230890)
Intended Use	Used for measurement of the electrolytes sodium, potassium and chloride in serum and urine for diagnosis and treatment of electrolyte imbalance	Used for measurement of the electrolytes sodium, potassium and chloride in serum and urine for diagnosis and treatment of electrolyte imbalance
Method	Direct	Direct
Calibration Frequency	8 Hours	8 Hours
ISE Electrodes Usage [10 000 Samples]	REF: 360 Days	REF: 360 Days
	Na^+: 360 Days	Na^+: 360 Days
	K^+: 180 Days	K^+: 180 Days
	Cl^-: 90 Days	Cl^-: 90 Days
ISE Sample Types	Serum	Serum
	Urine	Urine
Environmental Operating Temperature	15°C to 30°C	15°C to 30°C

Differences

Parameter	RX imola Automated Analyzer With previous ISE unit (ORIGINALLY CLEARED DEVICE K052914)	RX imola Automated Analyzer With New ISE Unit (CANDIDATE DEVICE K230890)
ISE Throughput	240 tests per hour	180 tests per hour
Consumables	Medica: Reference Electrode	Horiba: Reference Electrode
	Medica: Sodium Electrode (Na^+)	Horiba: Sodium Electrode (Na^+)
	Medica: Potassium (K^+)	Horiba: Potassium (K^+)
	Medica: Chloride (Cl^-)	Horiba: Chloride (Cl^-)
	Medica: CAL A	Horiba: L-Solution
	Medica: CAL B (Calibrator)	Horiba: H-Solution (Calibrator)
	Medica: Clean Solution	Horiba: Clean Solution
	Medica: Urine Diluent (for urine ISE)	Horiba: Urine Diluent (for urine ISE)
		Horiba: Etching Solution
		Horiba: Ref-Solution
Sample Volume	70ul	53ul
Calibration Type	2-Point (CAL A + CAL B)	2-Point (L-solution + H-Solution)
Analysis Time	Serum - 30s including 1-point calibration	Serum - 36s including 1 point calibration
	Urine - 60s including 1-point calibration	Urine - 54s including 1 point calibration
ISE Module Size	100mm (H) x 102mm (W) x 91 mm (D)	175mm (H) x 205mm (W) x 95 mm (D)
Maximum Environmental Temperature (Unopened Storage)	38°C	45°C
Calibration Pass Range	Na^+ pass range (50 mV - 66 mV)	Na^+ pass range (38 mV - 65 mV)
	K^+ pass range (50 mV - 63 mV)	K^+ pass range (37 mV - 67 mV)
	Cl^- pass range (40 mV - 59 mV)	Cl^- pass range (28 mV - 53 mV)

ANALYTICAL PERFORMANCE:

Precision/Reproducibility:

Precision was evaluated consistent with C.L.S.I document EP05-A3 'Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline- Third Edition.' Serum precision studies were performed on two RX imola systems using two levels of control material and at least five human serum samples for Sodium, Potassium and Chloride. Urine precision studies were performed on the same two RX imola systems for Sodium, Potassium and Chloride using two levels of urine controls and at least five urine patient pools. Testing was conducted twice per day for 20 non-consecutive days. Two replicates per run was performed for each sample.

The results are summarized in the tables below:

Table 3: Sodium Serum Precision Summary

Within run precision

	Control 1	Control 2	Serum Pool 1	Serum Pool 2	Serum Pool 3	Serum Pool 4	Serum Pool 5	Serum Pool 6
Mean (mmol/l)	143.72	160.93	101.68	111.00	118.67	136.38	162.38	192.10
SD	0.88	1.01	0.69	0.59	1.88	0.47	2.69	0.37
CV (%)	0.6	0.6	0.7	0.5	1.6	0.3	1.7	0.2
n	80	80	80	80	80	80	80	80

Total precision

	Control 1	Control 2	Serum Pool 1	Serum Pool 2	Serum Pool 3	Serum Pool 4	Serum Pool 5	Serum Pool 6
Mean (mmol/l)	143.72	160.93	101.68	111.00	118.67	136.38	162.38	192.10
SD	1.57	2.17	2.11	1.39	2.37	1.63	3.61	3.71
CV (%)	1.1	1.4	2.1	1.3	2.0	1.2	2.2	1.9
n	80	80	80	80	80	80	80	80

Table 4: Potassium Serum Precision Summary

Within run precision

	Control 1	Control 2	Serum Pool 1	Serum Pool 2	Serum Pool 3	Serum Pool 4	Serum Pool 5	Serum Pool 6
Mean (mmol/l)	4.00	6.43	0.91	2.16	3.26	4.56	6.58	9.73
SD	0.02	0.04	0.02	0.01	0.01	0.03	0.04	0.05
CV (%)	0.6	0.7	1.9	0.4	0.4	0.8	0.6	0.5
n	80	80	80	80	80	80	80	80

Total precision

	Control 1	Control 2	Serum Pool 1	Serum Pool 2	Serum Pool 3	Serum Pool 4	Serum Pool 5	Serum Pool 6
Mean (mmol/l)	4.00	6.43	0.91	2.16	3.26	4.56	6.58	9.73
SD	0.04	0.09	0.04	0.04	0.04	0.06	0.09	0.20
CV (%)	0.9	1.4	4.1	1.6	1.3	1.2	1.4	2.1
n	80	80	80	80	80	80	80	80

Table 5: Chloride Serum Precision Summary

Within run precision

	Control 1	Control 2	Serum Pool 2	Serum Pool 3	Serum Pool 4	Serum Pool 5
Mean (mmol/l)	98.27	120.99	83.30	96.14	117.38	161.10
SD	0.68	0.95	0.79	0.94	0.50	0.74
CV (%)	0.7	0.8	1.0	1.0	0.4	0.5
n	80	80	80	80	80	80

Total precision

	Control 1	Control 2	Serum Pool 2	Serum Pool 3	Serum Pool 4	Serum Pool 5
Mean (mmol/l)	98.27	120.99	83.30	96.14	117.38	161.10
SD	1.04	1.54	1.85	1.02	1.06	3.55
CV (%)	1.1	1.3	2.2	1.1	0.9	2.2
n	80	80	80	80	80	80

Table 6: Sodium Urine Precision Summary

Within run precision

	Control 1	Control 2	Urine Pool 2	Urine Pool 3	Urine Pool 4	Urine Pool 5	Urine Pool 6
Mean (mmol/l)	65.45	215.33	84.72	118.01	179.59	257.99	285.71
SD	2.48	2.83	1.91	2.41	3.08	2.88	2.77
CV (%)	3.8	1.3	2.3	2.0	1.7	1.1	1.0
n	80	80	80	80	80	80	80

Total precision

	Control 1	Control 2	Urine Pool 2	Urine Pool 3	Urine Pool 4	Urine Pool 5	Urine Pool 6
Mean (mmol/l)	65.45	215.33	84.72	118.01	179.59	257.99	285.71
SD	3.85	8.94	3.18	3.19	4.71	6.11	7.16
CV (%)	5.9	4.2	3.8	2.7	2.6	2.4	2.5
n	80	80	80	80	80	80	80

Table 7: Potassium Urine Precision Summary

Within run precision

	Control 1	Control 2	Urine Pool 2	Urine Pool 3	Urine Pool 4	Urine Pool 5
Mean (mmol/l)	34.49	144.18	33.54	85.89	122.59	160.81
SD	0.32	0.93	0.21	0.82	0.77	1.73
CV (%)	0.9	0.6	0.6	1.0	0.6	1.1
n	80	80	80	80	80	80

Total precision

	Control 1	Control 2	Urine Pool 2	Urine Pool 3	Urine Pool 4	Urine Pool 5
Mean (mmol/l)	34.49	144.18	33.54	85.89	122.59	160.81
SD	0.77	4.80	0.73	2.49	4.10	6.50
CV (%)	2.2	3.3	2.2	2.9	3.3	4.0
n	80	80	80	80	80	80

Table 8: Chloride Urine Precision Summary

Within run precision

	Control 1	Control 2	Urine Pool 1	Urine Pool 2	Urine Pool 3	Urine Pool 4	Urine Pool 5	Urine Pool 6
Mean (mmol/l)	86.04	280.01	85.63	93.06	146.38	198.19	247.72	315.40
SD	2.28	2.68	1.91	2.13	2.19	2.41	2.69	4.24
CV (%)	2.7	1.0	2.2	2.3	1.5	1.2	1.1	1.3
n	80	80	80	80	80	80	80	80

Total precision

	Control 1	Control 2	Urine Pool 1	Urine Pool 2	Urine Pool 3	Urine Pool 4	Urine Pool 5	Urine Pool 6
Mean (mmol/l)	86.04	280.01	85.63	93.06	146.38	198.19	247.72	315.40
SD	2.93	7.57	2.97	3.33	3.67	4.53	7.66	8.12
CV (%)	3.4	2.7	3.5	3.6	2.5	2.3	3.1	2.6
n	80	80	80	80	80	80	80	80

Precision Conclusion

The acceptance criteria for precision was met for serum and urine for all analytes (Sodium, Potassium and Chloride) on the RX imola with the modified ISE device.

Linearity/assay reportable range:

Linearity studies have been carried out in serum and urine in accordance with C.L.S.I. standard EP6-A 'Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline'. Linearity studies were performed at 9 levels to determine the analytical range of an assay - that is the range where the reported result is a linear function to the analyte concentration (or where deviation from linearity is less than 5%).

The linearity samples were prepared at 9 levels to cover the measuring intervals in the table below.

Table 9: Linearity Results Summary

Analyte	Specimen Type	Measuring Interval (mmol/L)
Sodium	Serum	90 to 200
	Urine	45 to 318
Potassium	Serum	0.5 to 11
	Urine	7 to 168
Chloride	Serum	72 to 210
	Urine	61 to 319

Linearity Conclusion

The results of the linearity studies support the above claimed measuring ranges for serum and urine for all analytes (Sodium, Potassium and Chloride) on the RX imola with the modified ISE device.

Specificity/Interference

Evaluation of specificity/interference was carried out in serum and urine in accordance with EP07 3rd Edition 'Interference Testing in Clinical Chemistry.' The analytes below were tested in serum up to the following levels and were found not to interfere with Sodium, Potassium and Chloride determination.

ISE Sodium, Potassium and Chloride Interference Summary (in Serum)
The analytes below were added to normal serum and found not to interfere up to the following levels.

Table 10: Analytes Added to Normal Serum Level 1

	Sodium - 130 mmol/l	**Potassium – 3 mmol/l**	**Chloride – 90 mmol/l**
Haemoglobin	1000 mg/dl	126 mg/dl	1000 mg/dl
Total Bilirubin	60 mg/dl	60 mg/dl	60 mg/dl
Conjugate Bilirubin	60 mg/dl	60 mg/dl	49.5 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl	2000 mg/dl
Intralipid®	2000 mg/dl	2000 mg/dl	2000 mg/dl

Table 11: Analytes Added to Normal Serum Level 2

	Sodium - 150 mmol/l	**Potassium – 5 mmol/l**	**Chloride – 110 mmol/l**
Haemoglobin	1000 mg/dl	205 mg/dl	1000 mg/dl
Total Bilirubin	60 mg/dl	60 mg/dl	60 mg/dl
Conjugate Bilirubin	60 mg/dl	60 mg/dl	60 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl	2000 mg/dl
Intralipid®	2000 mg/dl	2000 mg/dl	2000 mg/dl

Table 12: Exogenous Interferences in Serum - Level 1

Interfering Substance	Sodium 130 mmol/l	Potassium 3 mmol/l	Chloride 90 mmol/l
Bromide	37.5 mmol/l	37.5 mmol/l	37.5 mmol/l
Ascorbic Acid	341 µmol/L	341 µmol/L	341 µmol/L
Thiocyanate	6.88 mmol/l	0.8 mmol/l	1.12 mmol/l
Lithium	3.2 mmol/l	3.2 mmol/l	3.2 mmol/l
Salicylic Acid	4.3 mmol/l	4.3 mmol/l	4.3 mmol/l

Table 13: Exogenous Interferences in Serum - Level 2

Interfering Substance	Sodium 150 mmol/l	Potassium 5 mmol/l	Chloride 110 mmol/l
Bromide	37.5 mmol/l	37.5 mmol/l	37.5 mmol/l
Ascorbic Acid	341 µmol/L	341 µmol/L	341 µmol/L
Thiocyanate	6.88 mmol/l	0.85 mmol/l	1.25 mmol/l
Lithium	3.2 mmol/l	3.2 mmol/l	3.2 mmol/l
Salicylic Acid	4.3 mmol/l	4.3 mmol/l	4.3 mmol/l

ISE Sodium, Potassium and Chloride Urine Interference (in urine) summary

The analytes below were added to normal urine and found not to interfere up to the following levels.

Table 14: Analytes Added to Normal Urine Specificity/Interference Level 1

	Sodium 40 mmol/l	Potassium 25 mmol/l	Chloride 110 mmol/l
Haemoglobin	590 mg/dl	765 mg/dl	1000 mg/dl
Total Bilirubin	17.4 mg/dl	60 mg/dl	60 mg/dl
Conjugate Bilirubin	22 mg/dl	60 mg/dl	44.5 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl	2000 mg/dl
Intralipid®	810 mg/dl	2000 mg/dl	2000 mg/dl

Table 15: Analytes Added to Normal Urine Specificity/Interference Level 2

	Sodium 220 mmol/l	Potassium 125 mmol/l	Chloride 250 mmol/l
Haemoglobin	1000 mg/dl	1000 mg/dl	1000 mg/dl
Total Bilirubin	60 mg/dl	60 mg/dl	60 mg/dl
Conjugate Bilirubin	60 mg/dl	60 mg/dl	60 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl	2000 mg/dl
Intralipid®	2000 mg/dl	2000 mg/dl	2000 mg/dl

Table 16: Exogenous Interferences in Urine - Level 1

Interfering Substance	Sodium 40 mmol/l	Potassium 25 mmol/l	Chloride 110 mmol/l
Ascorbic Acid	200 mg/dl	200 mg/dl	200 mg/dl
Boric Acid	1000 mg/dl	1000 mg/dl	1000 mg/dl
Ethanol	1000 mg/dl	1000 mg/dl	1000 mg/dl
Gamma Globulin	500 mg/dl	500 mg/dl	500 mg/dl
Glucose	2000 mg/dl	2000 mg/dl	2000 mg/dl
HSA	500 mg/dl	500 mg/dl	500 mg/dl

Table 17: Exogenous Interferences Level 2 (Urine)

Interfering Substance	Sodium 220 mmol/l	Potassium 125 mmol/l	Chloride 250 mmol/l
Ascorbic Acid	200 mg/dl	200 mg/dl	200 mg/dl
Boric Acid	1000 mg/dl	1000 mg/dl	1000 mg/dl
Ethanol	1000 mg/dl	1000 mg/dl	1000 mg/dl
Gamma Globulin	500 mg/dl	500 mg/dl	500 mg/dl
Glucose	2000 mg/dl	2000 mg/dl	2000 mg/dl
HSA	500 mg/dl	500 mg/dl	500 mg/dl

Method comparison with predicate device:

Correlation studies were carried out for serum and urine in accordance with C.L.S.I. guideline EP09c 'Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline- Third Edition'. A method comparison was conducted against the unmodified device (cleared under k052914) to confirm the device is substantially equivalent. Testing was conducted on two RX imola analysers, one RX imola analyser with the modified device, and the other RX imola analyser with the unmodified device.

Correlation (Serum)

Sodium

This method – RX imola new ISE unit (Y) was compared with method on the RX imola with previous ISE unit (X) and the following linear regression equation obtained: -

Y = 1.06x – 8.4

R = 0.973

105 patient serum samples were analysed spanning the range 111.7 to 195.8 mmol/l.

Potassium

This method – RX imola new ISE unit (Y) was compared with method on the RX imola with previous ISE unit (X) and the following linear regression equation obtained: -

Y = 1.02x – 0.09

R = 0.998

109 patient serum samples were analysed spanning the range 0.96 to 10.63 mmol/l.

Chloride

This method – RX imola new ISE unit (Y) was compared with method on the RX imola with previous ISE unit (X) and the following linear regression equation obtained: -

Y = 1.03x – 6.59

R = 0.987

104 patient serum samples were analysed spanning the range 86.2 to 196.2 mmol/l.

Correlation (Urine)

Sodium

This method – RX imola new ISE unit (Y) was compared with method on the RX imola with previous ISE unit (X) and the following linear regression equation obtained: -

Y = 0.92x + 6.43

R = 0.997

72 patient urine samples were analysed spanning the range 49.4 to 298.6 mmol/l.

Potassium

This method – RX imola new ISE unit (Y) was compared with method on the RX imola with previous ISE unit (X) and the following linear regression equation obtained: -

Y = 1.03x – 1.02

R = 0.999

84 patient urine samples were analysed spanning the range 9.5 to 167.6 mmol/l.

Chloride

This method – RX imola new ISE unit (Y) was compared with method on the RX imola with previous ISE unit (X) and the following linear regression equation obtained: -

Y = 0.89x + 18.49

R = 0.986

90 patient urine samples were analysed spanning the range 84.8 – 226.8 mmol/l.

DESIGN CONTROL ACTIVITIES

The verification and validation of the device modification has been performed under design control. The design control activities were based on the risk analysis and acceptance criteria were set to maintain the performance and safety of the device. The verification and validation includes in-house studies of precision, method comparison, interferences and linearity.

RISK ANALYSIS

A Risk Analysis was performed to identify any new risks associated with the change in the ISE electrodes provided with the RX imola. Based on this and the testing the results indicate that the changes to the ISE unit on the RX imola are safe and effective for the stated intended use and are substantially equivalent to the previously approved device.

OVERALL CONCLUSION

The modified device is substantially equivalent to the unmodified device (cleared under k052914).