K110520

Tokyo Boeki Medisys System Ltd.
1-14-21 Higashi-Toyoda, Hino, Tokyo 191-0052, Japan
Phone: +81-42-587-2965 Fax: ++81-42-587-7781

MAR 2 3 2012

510(k) SUMMARY

Submitter's Name/Address

Submitter's Name:	Tokyo Boeki Medisys Inc.
Submitter's Address:	1-14-21 Higashi-Toyoda, Hino Tokyo 197-0823
Phone:	+81-42-532-2771
Fax:	+81-42-532-2772
Establishment Registration Number:	3004378324
Owner/Operator Number:	9060135

Contact Person (United States Agent)

Name of Agent:	James M. Clinton
Agent's Business Name:	Quality and Regulatory Consulting, LLC
Street Address:	5105 Fairoaks Road Durham, NC 27712-2078
Phone:	919-247-0479
Fax:	919-287-2551
E-mail address:	clintonjm@earthlink.net

Date of Preparation of this Summary: January 6, 2012

Device Trade or Proprietary Name: Biolis 12i

Device Common Name: Clinical Chemistry Analyzer (with optional ISE Module)

Classification Numbers/Class:

75JJE,	Class I
75JGS,	Class II
75CEM,	Class II
75CGZ,	Class II
75CFR	Class II

Tokyo Boeki Medisys System Ltd.
1-14-21 Higashi-Toyoda, Hino, Tokyo 191-0052, Japan
Phone: +81-42-587-2965 Fax: ++81-42-587-7781

510(k) Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is : K110520

Description:

Using photometry, the Biolis 12i instrument measures the glucose concentration in serum by monitoring the change in absorbance at 340 nm. Additionally, the Biolis 12i with Ion-Selective Elective module additionally measures the concentration of the electrolytes, sodium, potassium and chloride in serum, using indirect potentiometry.

Intended Use:

The Biolis 12i is a discrete chemistry analyzer with ion-selective electrode (ISE), with direct quantitative measurement of sodium, potassium, chloride, and glucose in serum. It is a device intended for the in-vitro, spectrophotometric determination of general chemistry assays for clinical use. The Biolis 12i includes an optional Ion Selective Electrode (ISE) module for the measurement of sodium, potassium and chloride in serum. The Biolis 12i is not for Point-Of-Care testing. It is for vitro diagnostic use only.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

The Biolis 12i analyzer with glucose hexokinase assay is intended to measure glucose quantitatively in human serum. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic glycemia, and of the pancreatic isle cell carcinoma

Substantial Equivalence:

Substantial equivalence has been demonstrated between Sirrus (K0421169) running Glucose reagents (K971467) and the Biolis 12i for measuring glucose in serum. These analyzers are calibrated with known concentration calibrator material and both measure specific concentrations using photometry and electrolytes using identical ion selective electrode modules

In addition, substantial equivalence has been demonstrated between the Prestige 24i (K040958) and

the Biolis 12i with an optional Ion Selective Electrode Module for measuring sodium, potassium and chloride in serum. These two analyzers are used to analyze for electrolytes. These analyzers are calibrated with known concentration calibrator material and both utilize Ion-Selective Electrodes.

Comparison table with Sirrus (Glucose)

Item	New Device **Biolis 12i**	Predicate **Sirrus**(K042169)
General		
System Principle	Discrete, single line random access, multi-test analysis	Discrete, random access, multi-test analysis
Throughput	90 tests	240 tests
Configuration	Analytical unit, Control unit	Analytical unit, Control unit
Measurement modes	Absorbance	Absorbance
Detector	Photo-diode	Photo-diode
Optical system	Wavelength range of 340 to 800nm	Wavelength range of 340 to 800nm
Light source	Tungsten halogen lamp	Tungsten halogen lamp
Reaction cuvettes	Plastics, semi disposal	Plastics, semi disposal
Path length	8mm	8mm
Reaction time	Maximum 10min.	Maximum 10min.
Incubation temperature	37°C +/- 0.1°C	37°C +/- 0.1°C
Glucose		
Intended use	Quantitative determination of glucose in serum	Quantitative determination of glucose in serum
Method	Photometric endpoint using glucose hexokinase.	Photometric endpoint using glucose
Sample type	Serum	Serum,
Sample Volume	2 uL	3 uL
Wavelength	340 / 405 nm	340 / 405 nm
Reaction type	Endpoint	Endpoint
Read Point	Read period:19 - 20 cycles (30 seconds per cycle)	Read period: 50 - 52 cycles (15 seconds per cycle)

Comparison Table with Prestige 24i (ISE)

Item	New Device **Biolis 12i**	Predicate **Prestige 24i** (K040958)
General		
System Principle	Discrete, single line random access, multi-test analysis	Discrete, random access, multi-test analysis
Throughput	100 tests including ISE tests	400 tests including ISE tests
Configuration	Analytical unit, Control unit	Analytical unit, Control unit
Measurement modes	Absorbance	Absorbance
Detector	Photo-diode	Photo-diode
Optical system	Wavelength range of 340 to	Wavelength range of 340 to

	800nm	800nm
Light source	Tungsten halogen lamp	Tungsten halogen lamp
Reaction cuvettes	Plastics, semi disposal	Plastics, semi disposal
Path length	8mm	8mm
Reaction time	Maximum 10min.	Maximum 10min.
Incubation temperature	37°C +/- 0.1°C	37°C +/- 0.1°C
ISE	The ISE module is operated on the Biolis 12i integrated system.	The ISE module is operated on the Biolis 24i integrated system
Intended use	Quantitative determination of Na, K and Cl	Quantitative determination of Na, K and Cl
Method	Ion selective electrode	Ion selective electrode
Sample type	Serum	Serum,
Sample Volume	60 uL	60 uL
Analysis time	100 seconds	100 seconds

The validated system is described below.

Analyzer:	Tokyo Boeki BiOLiS 12i Analyzer with Ion -selective electrode module using direct potentiometry. Serial numbers are listed on individual study reports
Software	Interface software version: 1.70 ISE ROM software version: 3.05
Reagent:	Carolina Liquid Chemistries Glucose Reagent, Kit product no. BL-208 (also packaged as AU-208). Lot numbers are listed on individual study reports
Calibrator for glucose	Pointe Scientific Chemistry Calibrator product no. C7506-50, lot 11802, exp. March 2014 Premarket clearance reference no.: K070207
	The 185 mg/dL glucose set point for the Pointe Calibrator was verified for the Carolina Liquid Chemistries Glucose Reagent by comparing the calibrator to NIST SRM 965b, Glucose in Frozen Serum. The Pointe Calibrator was assayed eight times over each of four analytical runs against NIST standard levels 3 and 4 which were each assayed in duplicate. The glucose concentration of the Pointe Calibrator was calculated for each run by linear interpolation the NIST assay values and their respective certified values of 118.5 mg/dL and 294.5 mg/dL. The mean glucose result of the Pointe Calibrator over the four runs was 185.6 mg/dL.
Calibrator for ISE	Calibrator 1 and Calibrator 2 Manufacturer: Tokyo Boeki Medisys Lot numbers are listed on individual study reports Premarket clearance reference no: K040958

Tokyo Boeki Medisys System Ltd.
1-14-21 Higashi-Toyoda, Hino, Tokyo 191-0052, Japan
Phone: +81-42-587-2965 Fax: ++81-42-587-7781

Performance Characteristics:

ISE

A correlation analysis between the Prestige 24i and the Biolis 12i yielded the following results:

Representative Method		Correlation Coefficient	Slope (Least-Squares)	Y-axis intercept
1	Sodium	0.9872	1.0204	-3.1903
2	Potassium	0.9992	1.0255	-0.1457
3	Chloride	0.9922	0.9736	1.8580

The linearity test yielded the following results:

Linearity	
Sodium	100 - 200 mmol/L (Serum)
Potassium	1 - 10 mmol/L (Serum)
Chloride	70 - 200 mmol/L (Serum)

The precision test results:

		Item	Sample 1 %CV	Sample 2 %CV	Sample 3 %CV
4	Within Run N=20	Sodium	0.85	0.61	0.93
		Potassium	0.90	0.91	0.94
		Chloride	0.79	0.83	0.69
5	Day by Day-Run N=15	Sodium	0.4	0.4	0.3
		Potassium	0.8	0.9	0.4
		Chloride	1.0	0.7	0.4

Interferences

The Interference test yielded the following results:

No significant interference were observed for the substances at the concentration levels as follows

Substance	Normal	Abnormal
Bilirubin F	19.7 mg/dL	19.7 mg/dL
Bilirubin C	21 mg/dL	21 mg/dL
Hemoglobin	488 mg/dL	488 mg/dL
Lipemia	1000mg/dL	500 mg/dL

	Normal	Abnormal
Lithium Chloride	3.20 mmol/L	3.20 mmol/L
Sodium Bromide	37.60 mmol/L	37.60 mmol/L
Sodium Salicylate	4.34 mmol/L	4.34 mmol/L
Sodium Thiocyanate	6.88 mmol/L	6.88 mmol/L

Conclusion:

The Ion Selective Electrode performance data for Sodium, Potassium and Chloride demonstrates that Biolis 12i is substantially equivalent to the Prestige 24i (K040958).

Tokyo Boeki Medisys System Ltd.
1-14-21 Higashi-Toyoda, Hino, Tokyo 191-0052, Japan
Phone: +81-42-587-2965 Fax: ++81-42-587-7781

Glucose Reagent

Method Comparison

A correlation analysis between the Sirrus and the Biolis 12i yielded the following results:

Representative Method	Correlation Coefficient	Slope (Least-Squares)	Y-axis intercept
GLU	0.9975	1.0447	-4.845

Precision

The precision test results:

		Item	Sample 1 CV (%)	Sample 2 CV (%)	Sample 3 CV (%)
1	**Within-run N=20**	GLU	1.31	1.19	1.04
2	**Between-run N=20**	GLU	0.87	0.78	0.70

Linearity

The linearity test yielded the following results:

Correlation	0.9997
Slope	0.96
Intercept	-2.66
Range	25 - 540 mg/dL

Sensitivity

The minimum detection limit test yielded the following results:

Minimum Detectable value	7.83 mg/dL

Interferences

The Interference test yielded the following results:

No significant interference were observed at the following concentration levels

	Normal	Abnormal
Hemoglobin	500mg/dL	500mg/dL
Bilirubin	20 mg/dL	20 mg/dL
Lipemia	1000 mg/dL	1000 mg/dL

Stability Summary

The calibration stability test yielded the following results:

	Sample 1	Sample 2	Sample 3
CV (%)	2.1	2.5	2.1

Conclusion:

The glucose performance data demonstrates that Biolis 12i is substantially equivalent to Sirrus (K 042169)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Tokyo Boeki Medisys Inc.
c/o James Clinton
c/o Quality & Regulatory Consulting, LLC.
5105 Fairoaks Rd.
Durham, NC 27712

MAR 2 3 2012

Re: k110520
Trade Name: BIOLIS 12i
Regulation Number: 21 CFR §862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Codes: JGS, CEM, CGZ, CFR, JJE
Dated: February 29, 2012
Received: March 6, 2012

Dear Mr. Clinton:

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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110520

Device Name: Biolis 12i

Indications for Use:

The Biolis 12i is a discrete photometric chemistry analyzer with ion-selective electrode (ISE), with direct quantitative measurement of sodium, potassium, chloride, and glucose in serum. It is a device intended for the in-vitro, spectrophotometric determination of general chemistry assays for clinical use. The Biolis 12i includes an optional Ion Selective Electrode (ISE) module for the measurement of sodium, potassium and chloride in serum. The Biolis 12i is not for Point-Of-Care testing. It is for vitro diagnostic use only.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

The Biolis 12i analyzer with glucose hexokinase assay is intended to measure glucose quantitatively in human serum. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic glycemia, and of the pancreatic islet cell carcinoma.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) 110520