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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: K073018

Submitter:

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- **Contact Person:**

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- **Date Prepared:**

Mar. 5, 2007

Name of the device:

- **Trade/Proprietary Name:** BS-200 Chemistry Analyzer
- **Common Name:** Clinical Chemistry Analyzer (with optional ISE Module)
- **Classification Number/Class:**

75JJE, Class I
75CRF, Class II
75CEM, Class II
75CGE, Class II
75JGS, Class II

Legally Marketed Predicate Device:

K953239	Boehringer Mannheim/Hitachi 917 Analyzer
K000926	EasyElectroLyte/RapidLyte Na/K/Cl Analyzer
K002199	Liquid Glucose (Hexokinase) Reagent Set

Description:

The BS-200 Chemistry Analyzer is an automated clinical chemistry analyzer capable of performing various in vitro photometric assays. The Glucose was cleared under K002199 and is the chosen assay to demonstrate performance for the photometric unit. The BS-200 Chemistry Analyzer has an optional Ion-Selective Electrode (ISE) module which measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using ion selective electrode technology.

Intended Use:

The BS-200 Chemistry Analyzer is an automated chemistry analyzer for in vitro diagnostic use in clinical laboratories. The analyzer is designed for the in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebral spinal fluid samples.

Indications for Use:

The BS-200 Chemistry Analyzer is designed for clinical laboratory use, making direct quantitative measurements of Na+ (sodium), K+ (potassium), Cl-(chloride) in serum, plasma and urine samples and Glucose in serum samples. Additionally, other various chemistry assays may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

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.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Comparison of Technological Characteristics:

Substantial equivalence has been demonstrated between the BS-200 Chemistry Analyzer and Boehringer Mannheim/Hitachi 917 analyzer. Both of them utilize absorbance photometry to

perform and output quantitative results for kinetic and endpoint clinical chemistries. For analytes, the BS-200 Chemistry Analyzer and Boehringer Mannheim/Hitachi 917 analyzer determine the concentration of unknown samples from a standard curve generated with known analyte concentrations. Substantial equivalence has also been demonstrated between the BS-200 Chemistry Analyzer and EasyElectroLyte/RapidLyte Na/K/Cl Analyzer. Both of them are used to analyze for electrolytes. The analyzers are calibrated with known concentration calibrator material. The BS-200 Chemistry Analyzer and EasyElectroLyte/RapidLyte Na/K/Cl Analyzer both utilize Ion-Selective Electrodes technology.

Performance Characteristics:

Performance testing of the BS-200 Chemistry Analyzer consisted of running the FDA previously cleared assay and the ISE module on the BS-200 to evaluate precision, linearity, and method comparison, Limits of Detection and Limits of Quantitation, interference.

A correlation analysis between the BS-200 Chemistry Analyzer and the predicate devices yielded the following results:

Item	Regression Slope	Regression Intercept	Correlation Coefficient(r)	Sample numbers
GLU（mg/dL）	1.015	-0.0288	0.9992	60
K (mmol/L) serum(ISE)	0.9864	0.1226	0.9980	40
Na (mmol/L) serum(ISE)	0.9903	1.3158	0.9845	40
CL (mmol/L) serum(ISE)	0.9815	3.4021	0.9905	40
K (mmol/L)Urine(ISE)	0.9668	0.5307	0.9991	40
Na (mmol/L) Urine(ISE)	0.9479	-3.1284	0.9977	40
CL (mmol/L)Urine(ISE)	1.001	-6.9595	0.9887	40

The Within-Run precision test yielded the following results:

Glucose

Level I			Level II			Level III		
Mean	SD	CV	Mean	SD	CV	Mean	SD	CV
mg/dL	mg/dL	%	mg/dL	mg/dL	%	mg/dL	mg/dL	%
55.9	0.51	0.9%	121.5	0.73	0.6%	295.63	1.33	0.5%

ISE Chemistries

Item	Level I			Level II		
	Mean	SD	CV%	Mean	SD	CV%
K serum(ISE)	4.11	0.03	0.7%	6.77	0.05	0.8%

Na serum(ISE)	136.13	0.61	0.4%	146.74	0.72	0.5%
CL serum(ISE)	99.59	0.73	0.7%	115.68	0.52	0.5%
K Urine(ISE)	37.09	0.46	1.2%	67.49	0.63	0.9%
Na Urine(ISE)	99.23	1.13	1.1%	170.84	1.36	0.8%
CL Urine(ISE)	82.90	1.36	1.6%	132.16	1.24	0.9%

The Between-run imprecision test yielded the following results:

Glucose

Level I			Level II			Level III		
Mean	SD	CV	Mean	SD	CV	Mean	SD	CV
mg/dL	mg/dL	%	mg/dL	mg/dL	%	mg/dL	mg/dL	%
55.9	1.51	2.7%	121.5	2.46	2.0%	295.63	5.28	1.8%

ISE Chemistries

Item	Level I			Level II		
	Mean	SD	CV%	Mean	SD	CV%
K（mmol/L） serum(ISE)	4.11	0.07	1.6%	6.77	0.06	1.0%
Na（mmol/L） serum(ISE)	136.13	2.12	1.6%	146.74	1.66	1.1%
CL （mmol/L） serum(ISE)	99.59	1.78	1.8%	115.68	1.13	1.0%
K（mmol/L） Urine(ISE)	37.09	0.48	1.3%	67.49	0.70	1.0%
Na（mmol/L） Urine(ISE)	99.23	1.68	1.7%	170.84	2.41	1.4%
CL（mmol/L） Urine(ISE)	82.90	1.50	1.8%	132.16	2.12	1.6%

The linearity test yielded the following results:

Item	Linear range	
	Lower limit	Upper limit
GLU（mg/dL）	1	686
K (mmol/L) serum(ISE)	1.1	8.6
Na (mmol/L) serum(ISE)	113	194
CL (mmol/L) serum(ISE)	53	154

K (mmol/L)Urine(ISE)	13	184
Na (mmol/L) Urine(ISE)	27	372
CL (mmol/L)Urine(ISE)	42	422

The Limit of Detection test yielded the following results:

Item	LoB	LoD	LoQ
GLU（mg/dl）	0.04	0.22	0.97
K (mmol/L) serum(ISE)	0.1	0.16	0.42
Na (mmol/L) serum(ISE)	1.15	2.67	5.3
CL (mmol/L) serum(ISE)	2.95	5.0	12.0
K (mmol/L)Urine(ISE)	0.26	0.58	1.34
Na (mmol/L) Urine(ISE)	5.85	8.27	22.2
CL (mmol/L)Urine(ISE)	4.5	6.29	17.1

The Interference test yielded the following results:

Item	Interference materials		
	Hemoglobin	Bilirubin	Intralipids®
GLU（mg/dl）	250mg/dl	18 mg/dl	300mg/dl
K (mmol/L) serum(ISE)	>500mg/dl	>20mg/dl	>1000 mg/dl
Na (mmol/L) serum(ISE)	>500mg/dl	>20mg/dl	>1000 mg/dl
CL (mmol/L) serum(ISE)	>500mg/dl	>20mg/dl	>1000 mg/dl

Conclusion:

The data demonstrates that the BS-200 Chemistry Analyzer is substantially equivalent to Boehringer Mannheim/Hitachi 917 Analyzer and EasyElectroLyte/RapidLyte Na/K/Cl Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
c/o Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021 US

Re: k072018
Trade/Device Name: BS-200 Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CFR, JGS, CEM, CGZ, JJE
Dated: January 25, 2008
Received: January 28, 2008

Dear Ms. Goldstein Falk:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072018

Device Name: Na^+, K^+, Cl^-, glucose tests on the BS-200 Analyzer

Indication For Use:

The BS-200 Chemistry Analyzer is designed for clinical laboratory use, making direct quantitative measurements of Na+ (sodium), K+ (potassium), Cl-(chloride) in serum, plasma and urine samples and Glucose in serum samples. Additionally, other various chemistry assays may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

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Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Prescription Use _x_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) K072018