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SECTION 8
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 K120369.

807.92 (a)(1): Name: Hitachi Chemical Diagnostics
Address: 630 Clyde Court
Mountain View, CA 94043

Phone: (650) 961 5501
FAX: (650) 969 2745
Contact: Mr. Bunichiro Nakajima

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:
Hitachi Clinical Analyzer S TEST Reagent Cartridge for Glucose

Common Name: Routine chemistry analyzer for glucose (GLU)

Classification: 21 CFR § 862.1345- glucose test system (GLU)

807.92 (a)(3): Identification of the legally marketed predicate devices

Instrument portion: Roche/Hitachi cobas 8000 (c502 module)- K100853
Reagent Test Systems: Roche/Hitachi cobas 8000 (c502 module)- K100853, includes glucose

Integrated system (instrument): Alfa Wasserman S40 system- K072140

807.92 (a)(4): Device Description
The Hitachi Clinical Analyzer is an automatic, bench-top, wet chemistry system intended for use in clinical laboratories or physician office laboratories. The instrument consists of a desktop analyzer unit, an operations screen that prompts the user for operation input and displays data, a printer, and a unit cover. The analyzer unit includes a single probe, an incubation rotor, carousels for sample cups and reagent cartridges, and a multi-wavelength photometer. The single-use reagent cartridges may be placed in any configuration on the carousel, allowing the user to develop any test panel where the reagent cartridges are available.

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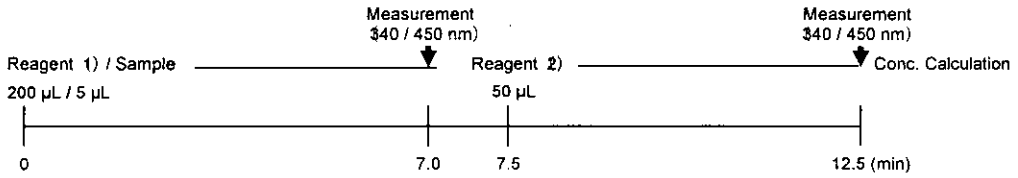
The S TEST reagent cartridges are made of plastic and include two small reservoirs capable of holding two separate reagents (R1 and R2), separated by a reaction cell/photometric cuvette. The cartridges also include a dot code label that contains all chemistry parameters, calibration factors, and other production-related information, e.g., expiration dating. The dimensions of the reagent cartridges are: 13.5 mm (W) × 28 mm (D) × 20.2 mm (H).

System operation: After the sample cup is placed into the carousel, the analyzer pipettes the sample, pipettes the reagent, and mixes (stirs) the sample and reagent together. After the sample and reagent react in the incubator bath, the analyzer measures the absorbance of the sample, and based on the absorbance of the reactions, it calculates the concentration of analyte in the sample. The test system can measure analytes in serum or plasma and results are available in approximately 15 minutes per test. This submission is for reagent cartridge test systems for glucose.

Chemistry reactions:
Glucose is phosphorylated to glucose-6-phosphate by hexokinase (HK) in the presence of ATP. When the glucose-6-phosphate is converted into 6-phosphogluconic acid by glucose-6-phosphate dehydrogenase (G6PD), NADP is converted into NADPH with an increase in absorbance at 340 nm. The concentration of glucose can be determined by measuring the amount of change in absorbance of NADPH.

$$\text{Glucose} + \text{ATP} \xrightarrow[Mg^{2+}]{\text{HK}} \text{Glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NADP} \xrightarrow{\text{G6PD}} \text{6-Phosphogluconic acid} + \text{NADPH}$$



807.92 (a)(5): Intended Use
The S TEST reagent cartridge for glucose is intended for the quantitative measurement of glucose in serum, lithium heparin plasma, K3 EDTA plasma, and sodium citrate plasma on the Hitachi Clinical Analyzer. The test system is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia.

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807.92 (a)(6): Technological Similarities and Differences to the Predicate
The following chart describes similarities and differences between the two test systems.

Characteristic	Hitachi S TEST Systems	PREDICATE(S)
Instrument Platform	Hitachi Clinical Analyzer	Roche cobas 8000 – K100853
		also, Alfa Wasserman S40- K072140
Glucose Test System	K number- K120369	Roche K number- K100853
Device Class, Regulation Code	Class II, 21 CFR 862.1345	Same
Classification Product Code	CFR	Same
Intended Use	Quantitative determination of glucose	Same
Testing Environment	Physician office or clinical lab	Clinical lab- cobas POL/Clin Lab - Alfa Wasserman
Test Principle	Enzymatic method (Hexokinase method)	UV Test- enzymatic reference method with hexokinase
Specimen Type	Human serum or plasma	Human serum, plasma, CSF, or urine
Reportable Range	5 to 500 mg/dL	2 to 750 mg/dL
Detection Wavelength	340/450 nm	700/340 nm
Detection Limit	5 mg/dL	2 mg/dL
Linearity	5 to 500 mg/dL	2 to 750 mg/dL
Precision	%CVs ranged from 2.1% to 3.9%	%CVs range from 0.7% to 1.3% (from product labeling)

807.92 (b)(1): Brief Description of Nonclinical Data
A series of studies were performed that evaluated the following nonclinical performance characteristics for glucose: analytical sensitivity (limits of detection), linearity, 20-day in-house precision, interference testing, in-house method comparisons, and matrices comparison between serum and various plasma options.

Analytical Sensitivity (Limits of Detection)
The study followed CLSI EP17. The sensitivity for glucose was calculated to be 0.3 mg/dL. In a second experiment with three low-level samples assayed 6 times a day for 3 days on three separate analyzers, the limit of quantitation (LoQ) was determined to be 5 mg/dL.

Linearity
The study followed CLSI EP-6A. The S TEST glucose is linear between 5 and 500 mg/dL.

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20-day In-house Precision
The studies followed CLSI EP5-A2, where three levels of samples were each tested four-times a day for 20 days. The results were as follows:

Precision Summary:

		Mean (mg/dL)	Within-Run %CV	Total %CV
Glucose	Level 1	73.0	3.9%	3.9%
n= 80 per level	Level 2	213.8	1.5%	2.1%
	Level 3	306.1	1.1%	3.0%

Interference Testing
The studies followed CLSI EP7-A2. The data demonstrated that the S TEST for glucose was not affected by high levels of the following substances at the levels noted:

- Hemoglobin: no interference up to 1000 mg/dL hemoglobin for glucose around 200 mg/dL and up to 500 mg/dL hemoglobin for low glucose levels (~50 mg/dL).
- Unconjugated bilirubin no interference up to 50 mg/dL bilirubin for glucose around 200 mg/dL and up to 6.25 mg/dL bilirubin for low glucose levels (~50 mg/dL).
- Triglyceride: no interference up to 800 mg/dL triglycerides.
- Ascorbic acid: no interference up to 50 mg/dL ascorbic acid.

Method Comparisons
The method comparison study evaluated 100 serum samples; matched aliquots were assayed with both the Hitachi Clinical Analyzer with S TEST GLU reagent cartridge and the Roche/Hitachi cobas 6000. The data were analyzed by least squares linear regression (Hitachi = y-axis), and the results were as follows:

Glucose (mg/dL)
n= 100
y= 0.99x -2.7
correlation coefficient (r) = 0.994
95% confidence interval of the slope = 0.98 to 1.02; 95% confidence interval of the y-intercept = -5.5 to 0.8

Matrices Comparisons
A study was performed to validate the use of sodium citrate, lithium heparinized, and K3 EDTA plasma as alternatives to serum for the Hitachi Clinical Analyzer with S TEST GLU reagent cartridges Thirty-eight (38) matched serum/plasma samples that spanned the glucose dynamic range were assayed in singleton and the results were compared using least squares liner regression (plasma = y-axis). The performance characteristics were as follows.

N = 38
Range (serum) = 12 to 441 mg/dL

	Na Citrate Plasma	Heparinized Plasma	EDTA Plasma
Slope (95% CIs)	0.98 (0.96 to 1.00)	1.00 (0.98 to 1.02)	1.00 (0.99 to 1.02)
y-intercept (95% CIs)	-4.6 (-8.2 to -0.8)	-2.1 (-5.8 to 1.6)	-0.3 (-3.1 to 2.6)
r	0.998	0.998	0.999

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807.92 (b)(2): Brief Description of Clinical Data

Studies for precision and method comparison (accuracy) were performed at three external POL-type sites to evaluate the Hitachi Clinical Analyzer with S TEST GLU reagent cartridge in one of its targeted intended use environments, the physician's office laboratory.

For the external site precision study, each site received three blinded serum samples (the Precision Panel, labeled A, B, and C) that were chosen to represent low, intermediate, and high concentrations of each analyte. Each sample was assayed six times per day for five days, reporting 30 results per level per analyte. Precision estimates for within-run precision and total precision were as follows:

Glucose (mg/dL)

n = 30 replicates per sample per site

Site	Sample	Mean	Within-run Precision		Total Precision	
			SD (mg/dL)	%CV	SD (mg/dL)	%CV
Site 1	A	59.3	2.6	4.5%	2.8	4.6%
Site 2	A	59.1	0.7	1.1%	1.0	1.7%
Site 3	A	59.1	1.2	2.1%	1.4	2.3%
Site 1	B	117.3	4.0	3.4%	4.4	3.7%
Site 2	B	117.7	0.9	0.8%	1.3	1.1%
Site 3	B	114.9	1.6	1.4%	1.7	1.7%
Site 1	C	358.7	11.5	3.2%	12.8	3.6%
Site 2	C	354.8	3.5	1.0%	6.8	1.9%
Site 3	C	343.9	7.1	2.1%	10.2	3.0%

For the external site method comparisons study, each POL site received approximately 50 blinded serum samples that were chosen to represent as full a range of analyte concentrations as possible, and a central laboratory received a matched aliquot for each serum sample. Each sample was assayed by the Hitachi system at the POL sites, and by the Roche cobas 6000 (predicate system) at the central laboratory. The results were analyzed by least squares linear regression (Hitachi = y-axis), and the performance characteristics were as follows:

POL ACCURACY DATA SUMMARY- GLU mg/dL

Site #	n	Range	Regression Equation	"r"	CI* Slope	CI Intercept
1	53	75 to 375	y = 1.01x -1.1	0.99	0.99 to 1.02	-2.7 to 0.6
2	52	69 to 361	y = 0.97x -0.1	0.99	0.96 to 0.99	-2.1 to 1.9
3	51	75 to 399	y = 1.05x -2.5	0.99	1.03 to 1.07	-5.1 to 0.1

*95% Confidence Interval

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Hitachi Clinical Analyzer with the S TEST GLU reagent cartridge. The test system was shown to be safe and effective for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Hitachi Chemical Diagnostics, Inc.
c/o Erika B. Ammirati
575 Shirlynn Court
Los Altos, CA 94022

MAY 10 2012

Re: k120369
Trade Name: Hitachi Clinical Analyzer S TEST Reagent Cartridge for Glucose
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CFR
Dated: April 20, 2012
Received: April 23, 2012

Dear Ms. Ammirati:

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/MedicalDevices/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 Form

510(k) Number (if Known): **K120369**

Device Name:
Hitachi Clinical Analyzer S TEST Reagent Cartridge for Glucose (GLU)

Indications for Use:
The S TEST reagent cartridge for glucose is intended for the quantitative measurement of glucose in serum, lithium heparin plasma, K3 EDTA plasma, and sodium citrate plasma on the Hitachi Clinical Analyzer. The test system is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia.

Prescription Use __X__ (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 IF 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) 120369