K062118

510 (k) Summary

JUL 13 2007

1. Submitter Information

Company name:	Pointe Scientific, Inc.
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Date Prepared:	July 24th, 2006

2. Name of Device

Trade Names:	Pointe 360 Glucose Hexokinase Reagent Set
Common Name:	Glucose Assay
Regulation:	Glucose Test System, Class II, 21 CFR 862.1345

3. Predicate Device

Trade/Proprietary Name:	Roche Diagnostics Glucose/HK on the Hitachi 917
Submitter	Roche Diagnostics Systems Inc.
510 (k) Number	k953847

4. Device Description

The Pointe 360 is a computerized bench top laboratory instrument. It is capable of automating all stages of assay processing that involve incubation, reagent delivery, mixing, optical reading, calculating, data storage and reporting within specified limits. The glucose reagent set for the Pointe 360 is an assay for the determination of glucose in plasma or serum.

5. Intended Use

The Glucose Hexokinase reagent set is intended to be used in a diagnostic laboratory setting by qualified laboratory technologists for the quantitative determination of glucose in human serum and plasma on the Pointe 360 Analyzer. It is for in vitro diagnostic use only. The determination of glucose in serum and plasma is for use in the diagnosis and treatment of diabetes mellitus.

6. Comparison to Predicate Device

The Pointe 360 Glucose Hexokinase reagent set is substantially equivalent to the Roche Diagnostics Glucose/HK on the Hitachi 917 (k953847). Both reagent sets for each analyzer have a similar intended use and functionality.

Characteristics	Liquid Glucose (Proposed Device) and Pointe 360 analyzer	Roche Diagnostics Glucose/HK (Predicate Device) and Hitachi 917
Intended Use	The Glucose reagent set is intended to be used in a diagnostic laboratory setting bu qualified laboratory technologists for the quantitative determination of glucose in human serum.	Enzymatic in vitro test for the quantitative determination of glucose in human serum, plasma, urine and CSF.
Reagent	Hexokinase (yeast) 4000 U/L, G6PDH (Leuconostoc Mesenteroides) 4000 U/L, ATP 6.0 mM, NAD 3.0 mM, Bufffer pH 7.5 $\pm$ 0.1. Nonreactive stablizers and sodium azide (0.1%) as preservative.	R1: Tris Buffer: 100mmol/L, pH 7.8; Mg:4mmol/L; ATP $\geq$ 1.7 mmol/L; NADP $\geq$ 1.0 mmol/L; preservative R2: HEPES buffer, 30 mmol/L, pH 7.0; Mg:4mmo/L; HK $\geq$ 8.3 U/ml (yeast); G6PDH $\geq$ 15 U/ml (E. coli); preservative.

Format	Reagent provided as a ready to use liquid.	Reagents are provided in a ready to use format.
Stability	•Shelf life is 18 months when stored tightly capped at 2-8°C. • Once opened the reagent is stable at least 30 days when properly stored and handled.	Reagent is stable until the expiration date stated on the label at 2-8°C. Opened vial stability is 28 days at 2-8°C. Specific Shelf life not indicated.
Linearity / Assay range	1.0 – 500.0 mg/dl	2.0 – 750 mg/dl
Low Limit of Detection	1.0 mg/dl	2.0 mg/dl
Interference	No interference was observed from bilirubin up to 16.0 mg/dl, hemoglobin up to 300 mg/dl and lipemia (intralipid) up to 1000 mg/dl. (using a criteria of >10% variance from control) This data was generated using the Pointe 360 analyzer.	No significant (> 10.0%) lipemic interference found at Intralipid levels from 1-1000 mg/dl (0-3000 mg/dl Triglyceride). No significant (> 10.0%) icteric interference at Bilirubin levels of 60 mg/dl. No significant (> 10.0%) Hemoglobin levels of 1000 mg/dl.
Precision (Within Day)	Mean SD CV N Sample 1 81 0.6 0.7 % 20 Sample 2 276 1.1 0.4 % 20 Sample 3 468 4.9 1.0 % 20	Mean CV N Sample 1 127 1.0 % 63 Sample 2 66 1.1 % 63 Sample 3 274 0.8 % 63
Precision (Day to Day)	Mean SD CV N Sample 1 81 1.3 1.6 % 20 Sample 2 261 3.2 1.2 % 20 Sample 3 451 7.5 1.7 % 20	Mean CV N Sample 1 126 1.7 % 63 Sample 2 118 1.9 % 63 Sample 3 253 1.9 % 63
Correlation	Corr. Coefficient : Reg. Equation	Corr. Coefficient : Reg. Equation
Serum	0.996 y = 0.960x + 3.1	0.999 y = 1.02x -2.72
Plasma	0.997 y = 0.977x + 0.6	Not listed

7. Performance Studies

Testing of the Pointe 360 included validation of the assay as well as the software that is used for the instrument.

8. Conclusion

We feel the data supports a determination that the Pointe Scientific, Inc. Liquid Glucose Hexokinase reagent when used on the Pointe 360 performs and produces data that is substantially equivalent to the products marketed by Roche Diagnostics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 13 2007

Pointe Scientific, Inc.
c/o Mr. Ron Jamison
Technical Service Manager
5449 Research Drive
Canton, MI 48188

Re: k062118
Trade/Device Name: Pointe 360 Glucose Hexokinase Reagent
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: June 20, 2007
Received: June 22, 2007

Dear Mr. Jamison:

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

Indications for Use

510(k) Number (if known): k062118

Device Name: Glucose Hexokinase Reagent

Indications For Use:

The Glucose Hexokinase reagent set is intended to be used in a diagnostic laboratory setting by qualified laboratory technologists for the quantitative determination of glucose in human serum and plasma on the Pointe 360 Analyzer. It is for In Vitro diagnostic use only. The determination of glucose in serum and plasma is for use in the diagnosis and treatment of diabetes mellitus.

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

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