K103557

APR 27 2011

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

Submitter's name:	Diazyme Laboratories
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Date the Summary was Prepared:	April 19, 2011
Name of the Device	hsCRP Assay Kit hsCRP Assay Calibrator Set hsCRP Assay Control Set
Trade Name:	Diazyme hsCRP Assay Kit Diazyme hsCRP Assay Calibrator Set Diazyme hsCRP Assay Control Set
Common/Usual Name	CRP Assay
Device Classification Name	hsCRP Test System
Product code:	DCK (Cardiac C-Reactive Protein, Antigen, Antiserum, and Control) JIT – Calibrator, Secondary JJX – Single (specified) Analyte Controls (Assayed and Unassayed)
Panel:	Immunology (82)
Submission Type	510k

Regulation Number	21CFR 866.5270
Device Class	Class II

Predicate Device:

Roche TINA-QUANT CRP (LATEX) HS TEST SYSTEM (C-REACTIVE PROTEIN (LATEX) HIGH SENSITIVE)

Manufacturing Address	Diazyme Laboratories 12889 Gregg Court Poway, CA 92121 USA
Establishment Registration	2032900

Description of the Device:

Clinical Significance

CRP (C-reactive protein) is an acute phase protein whose concentration is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infectious, histolytic disease and a variety of disease states. Originally discovered by Tillet et al. in 1930 in patient sera with acute infection, CRP has now come to be used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to therapy and surgery. Furthermore, regular measurements of CRP in infants can be a useful aid in the early diagnosis of infectious disease.

Assay Principle

Diazyme hsCRP assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known concentration.

Diazyme hsCRP Assay calibrator set is intended for use with the Diazyme hsCRP Assay kit. Five calibration levels are needed for each run. Calibrators are treated exactly the same as patient samples.

Diazyme hsCRP Assay 3-point control set is intended for use with the Diazyme hsCRP Assay kit. Controls are treated exactly the same as patient samples. The quality controls assist laboratory users in verification steps ensuring that the assay reagents are functioning correctly.

Users are instructed to verify the calibration curve with the controls and run controls each time a new lot of reagents are received.

Indications for Use:
The Diazyme high sensitivity C-reactive protein (hsCRP) assay is for the *in vitro* quantitative determination of C-reactive protein (CRP) in human serum and plasma on automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. For *in vitro* diagnostic use only.

The Diazyme hsCRP assay Calibrator set is intended for use in the calibration of the C-reactive protein (CRP) assay. For *in vitro* diagnostic use only.

The Diazyme hsCRP assay Control set is intended for use as quality controls for the Diazyme hsCRP assay. For *in vitro* diagnostic use only.

Table 1 Summary of Assay Kit Components

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay
Reagent 1 buffer solution, ready to use Reagent 2 Suspension of anti-human CRP coated latex particles, ready to use Calibrators Ready to use liquid calibrators containing C-reactive protein	<u>Reagent 1</u> 100 mM Tris-buffer solution with 0.09% sodium azide, ready to use <u>Reagent 2</u> Suspension of latex particles (< 0.5%) coated with goat anti-human CRP with 0.09% sodium azide, ready to use. <u>Calibrators</u> Ready to use liquid calibrators prepared from human serum, purified human C-reactive protein, and 0.09% sodium azide
Calibrator set	Calibrator set
1 x 1.0 mL Calibrator 0 1 x 1.0 mL Calibrator 1 1 x 1.0 mL Calibrator 2 1 x 1.0 mL Calibrator 3 1 x 1.0 mL Calibrator 4 1 x 1.0 mL Calibrator 5	1 x 1.0 mL Calibrator 1 1 x 1.0 mL Calibrator 2 1 x 1.0 mL Calibrator 3 1 x 1.0 mL Calibrator 4
Control Set serum based	Control Set serum based
3 x 1.0mL Control 1 3 x 1.0mL Control 2	1 x 3.0mL Control 1 1 x 3.0mL Control 2 1 x 3.0mL Control 3

Comparison of new device to predicate: The charts below identify similarities and differences between the predicate device and the Diazyme hsCRP Assay.

Indications for Use

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay	Equivalency
The Tina-quant® CRP (Latex) High Sensitive Immmunoturbidimetric assay is for the in vitro quantitative determination of C-reactive protein (CRP) in human serum and plasma on Roche automated clinical chemistry analyzers. Highly sensitive measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. Measurement of CRP may also be used as an aid in the assessment of the risk of future coronary heart disease. When used as an adjunct to other laboratory evaluation methods of acute coronary syndromes, it may also be an additional independent indicator of recurrent event prognosis in patients with stable coronary disease or acute coronary syndrome.	The Diazyme high sensitivity C-reactive protein (hsCRP) assay is for the *in vitro* quantitative determination of C-reactive protein (CRP) in human serum and plasma on automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. For *in vitro* diagnostic use only.	Same except for cardiac claim with Roche

Principle

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay	Equivalency
Particle-enhanced immunoturbidimetric assay • Sample and addition of R1 (buffer) • Addition of R2 (anti-CRP antibody-latex) and start of reaction: Anti-CRP antibodies coupled to latex microparticles react with antigen in the sample to form an antigen/antibody complex. Following agglutination, this is measured turbidimetrically.	Diazyme's CRP assay is based on a latex enhanced immunoturbidimetric assay. When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the quantity of CRP in the sample. The actual concentration is then determined by the interpolation from a calibration curve prepared from calibrators of known concentration.	Same

Test Objective

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay	Equivalency

For the *in vitro* quantitative determination of CRP in human serum or plasma.	For the *in vitro* quantitative determination of CRP in human serum or plasma.	Same

Type of Test

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay	Equivalency
Quantitative	Quantitative	Same

Specimen Type

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay	Equivalency
Human serum or plasma.	Human serum or plasma.	Same

Product Type

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay	Equivalency
Assay reagent kit, calibrator kit, quality control kit.	Assay reagent kit, calibrator kit, quality control kit.	Same

Performance

Roche Tina-Quant CRP k042485	Diazyme hsCRP Assay
Working Range: 0.1-20 mg/L CRP Precision: CV% of 0.43 – 5.7% Accuracy (vs Dade-Behring N hsCRP): Correlation Coefficient: 0.996 Slope/Intercept: y = 1.06/-0.19	Linear Range: 0.2-20 mg/L CRP Precision: CV% of 0.7% - 7.3% Accuracy (vs. Roche Tina-Quant hsCRP): Correlation Coefficient: 0.99 Slope/ y Intercept: y = 1.01/0.0196

Calibrator Comparison

C.f.a.s. Proteins k011226	Diazyme hsCRP Assay	Equivalency
Separately packaged lot specific calibrator kit. Liquid stable.	Separately packaged lot specific calibrator kit. Liquid stable.	Same

Control Comparison

Roche CRP T Control N k982087, Precinorm Protein Control k871027	Diazyme hsCRP Assay	Equivalency
Separately packaged quality control kit designed for specific assay.	Separately packaged quality control set designed for specific assay.	Same

Performance Testing Summaries:

Method Comparison Study Summary
Human serum samples were tested with the Diazyme hsCRP Assay and the obtained results were compared to the predicate method. A total of 57 samples (ranging from 0.19 to 18.97 mg/L of CRP) were tested in both assays. The above described accuracy study showed that the Diazyme hsCRP Assay results correlated well with predicate method with a correlation coefficient of 0.99 with a slope of 1.0133 and 0.0196 y intercept.

	Serum Samples
n	57
Slope	1.0133
Intercept	0.0196
Correlation coeffi-	0.99
Range of values	0.19 to 18.97 mg/L of CRP

Precision Study Summary
The precision of the Diazyme hsCRP Assay was evaluated according to Clinical and Laboratory Standards Institute EP5-A guideline. In the study, three levels of serum based controls containing approximately 0.8, 1.6, and 8.7 mg/L of CRP, and a serum sample containing approximately 3.6 mg/L of CRP respectively was tested with 2 runs per day in duplicates over 20 working days. An additional serum sample containing approximately 15.6 mg/L of CRP was tested with 2 runs per day in duplicates over 5 days. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following table:

Within-Run Precision

	Level 1:	Level 2:	Level 3:	Serum	Serum
N	80	80	80	80	20
Mean	0.85	1.75	8.62	3.62	15.56
SD	0.03	0.03	0.06	0.05	0.19
CV%	4.0%	1.7%	0.7%	1.4%	1.2%

Total Precision

	Level 1:	Level 2:	Level 3:	Serum	Serum
N	80	80	80	80	20
Mean	0.85	1.75	8.62	3.62	15.56
SD	0.04	0.05	0.12	0.09	0.24
CV%	4.2%	2.6%	1.4%	2.4%	1.6%

Conclusion:
For three levels of CRP controls, 20-day reproducibility data showed that the Within-Run Precision was from 0.7 % to 4.0 % and the Total Precision was from 1.4 % to 4.2%. For one serum sample, 20-day reproducibility data showed that the Within-Run Precision was 1.4 % and the

Total Precision was 2.4 %. For one serum sample, 5-day reproducibility data showed that the Within-Run Precision was 1.2 % and the Total Precision was 1.6 %.

Interference Study Summary

The following substances normally present in the blood produced less than 10% deviation when tested at levels equal to the concentrations listed below:

Interference	Concentration
Triglyceride	1000 mg/dL
Ascorbic Acid	176 mg/dL
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	500 mg/dL
Rheumatoid Factor	400 IU/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Diazyme Laboratories
c/o Dr. Abhijit Datta
Director, Technical Operations
12889 Gregg Court
Poway, CA 92064

APR 27 2011

Re: k103557
Trade Name: Diazyme high sensitivity C-reactive protein (hsCRP) assay kit; Diazyme high sensitivity C-reactive protein (hsCRP) assay calibrator set; Diazyme high sensitivity C-reactive protein (hsCRP) assay control set
Regulation Number: 21 CFR §866.5270
Regulation Name: C-reactive protein, Antigen, Antiserum and Control
Regulatory Class: Class II
Product Codes: DCK, JIT, JJX
Dated: April 19, 2011
Received: April 20, 2011

Dear Dr. Datta:

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 C. Harper, Ph.D.
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): k103557

Device Name: Diazyme high sensitivity C-reactive protein (hsCRP) assay kit, Diazyme high sensitivity C-reactive protein (hsCRP) assay calibrator set, Diazyme high sensitivity C-reactive protein (hsCRP) assay control set.

Indications for Use:

The Diazyme high sensitivity C-reactive protein (hsCRP) assay is for the *in vitro* quantitative determination of C-reactive protein (CRP) in human serum and plasma on automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. For *in vitro* diagnostic use only.

The Diazyme hsCRP assay calibrator set is intended for use in the calibration of the C-reactive protein (CRP) assay. For *in vitro* diagnostic use only.

The Diazyme hsCRP assay control set is intended for use as quality controls for the Diazyme hsCRP assay. For *in vitro* diagnostic use only.

Prescription Use X	AND/Or	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(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 Device Evaluation and Safety (OIVD)

Carol C. Benson

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

510(k) K103557