K083465

FEB 27 2009

510(k) Summary of Safety and Effectiveness for the Dimension Vista® Creatine Kinase Flex® Reagent Cartridge (K2038) Dimension Vista® Creatine Kinase MB Flex® Reagent Cartridge (K2032)

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.

A. 510(k) Number: K083465

B. Date of Preparation: November 18, 2008

C. Proprietary and Established Names:

Dimension Vista® Creatine Kinase (CKI) Flex® Reagent Cartridge (K2038)
Dimension Vista® Creatine Kinase MB (MBI) Flex® Reagent Cartridge (K2032)

D. Applicant:

Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101
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F. Regulatory Information:

Dimension Vista® Creatine Kinase (CKI) Flex® Reagent Cartridge (K2038)
1. Regulation section: 21 CFR § 862.1215 - Creatine phosphokinase/creatine kinase or isoenzymes test system
2. Classification: Class II
3. Product Code: CGS, Nad reduction/nadh oxidation, cpk or isoenzymes
4. Panel: Clinical Chemistry

Dimension Vista® Creatine Kinase MB (MBI) Flex® Reagent Cartridge (K2032)
1. Regulation section: 21 CFR § 862.1215 - Creatine phosphokinase/creatine kinase or isoenzymes test system
2. Classification: Class II
3. Product Code: JHS, Differential rate kinetic method, cpk or isoenzymes
4. Panel: Clinical Chemistry

F. Predicate Devices:
Dimension® (CKI) Flex® Reagent Cartridge (DF38) – K081731
Dimension® (MBI) Flex® Reagent Cartridge (DF32) – K081731

G. Device Description:

Dimension Vista® (CKI) Flex® Reagent Cartridge (K2038)
In a coupled enzyme reaction, the creatine kinase in patient samples catalyzes the transphosphorylation of phosphate from creatine phosphate to adenosine-diphosphate

(ADP) producing adenosine-triphosphate (ATP). Hexokinase (HK) phosphorylates glucose from the ATP to phosphorylate glucose. The resulting glucose-6-phosphate is oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) with the simultaneous reduction of nicotinamide adenine dinucleotide phosphate (NADP). The rate of formation of NADPH is directly proportional to the CK activity in the sample and is measured bichromatically at 340 and 540 nm.

Dimension Vista® (MBI) Flex® Reagent Cartridge (K2032)
The activity of the CK-MM isoenzyme is inhibited by an antibody specific for the CK-M subunit. The activity of the B subunit of creatine kinase MB isoenzyme is not inhibited, and it is on this basis that CK-MB can be measured.
In an enzyme coupled reaction, creatine kinase in patient samples catalyzes the transphosphorylation of creatine phosphate to adenosine-diphosphate (ADP), producing adenosine-triphosphate (ATP). Hexokinase (HK) uses the ATP to phosphorylate glucose. The resulting glucose-6-phosphate is oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) with the simultaneous reduction of nicotinamide adenine dinucleotide phosphate (NADP) to NADPH.
The rate of formation of NADPH is measured bichromatically at 340, 540 nm and is directly proportional to CK-B activity in the sample

H. Intended Use:

Dimension Vista® (CKI) Flex® Reagent Cartridge (K2038)
The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.
Dimension® (MBI) Flex® Reagent Cartridge (K2032)
The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

I. Substantial Equivalence Information:
The Dimension Vista® (CKI) Flex® Reagent Cartridge (K2038) and (MBI) Flex® Reagent Cartridge (K2032) were compared to the Dimension® predicate devices CKI (DF38) and MBI (DF32) previously cleared under K081731. A comparison of the important similarities and differences between the devices and the predicates is provided in the following tables:

Feature	Dimension Vista® (CKI) Flex® Reagent Cartridge (K2038)	Dimension® (CKI) Flex® Reagent Cartridge (DF38) K081731
Intended Use	The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension Vista® Clinical Chemistry System.	The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension® Clinical Chemistry System.
Device Technology(detection)	Bichromatic rate	Bichromatic rate
Measuring Range	7 – 1000 U/L	7 – 1000 U/L
Limit of Detection	7 U/L	7 U/L

Feature	Dimension Vista® (MBI) Flex® Reagent Cartridge (K2032)	Dimension® (MBI) Flex® Reagent Cartridge (DF32) K081731
Intended Use	The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension Vista® clinical chemistry system.	The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension® clinical chemistry system.
Device Technology (detection)	Bichromatic rate	Bichromatic rate
Measuring Range	3 - 125 U/L	3 - 125 U/L
Analytical Sensitivity	3 U/L	3 U/

J. Conclusion:

The Dimension Vista® CKI (K2038) and MBI (K2032) Flex® Reagent Cartridges are substantially equivalent to the Dimension® CKI (DF38) and MBI (DF32) Flex® Reagent Cartridges previously cleared under K081731. Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
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Newark, DE 19714-6101

FEB 27 2009

Re: k083465
Trade/Device Name: Dimension Vista® (CKI) Flex® Reagent Cartridge
Dimension Vista® (MBI) Flex® Reagent Cartridge
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: CGS, JHS
Dated: January 27, 2009
Received: January 28, 2009

Dear Mr. Carrio:

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

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

Indication for Use

510(k) Number (if known): K083465

Device Name:

Dimension Vista® (MBI) Flex® Reagent Cartridge

Indication For Use:

The creatine kinase MB (MBI) method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB isoenzyme activity in human serum and plasma on the Dimension Vista® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Dimension Vista® (CKI) Flex® Reagent Cartridge

Indication For Use:

The CKI method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase in human serum and plasma on the Dimension Vista® clinical chemistry system. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

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) K083465