K120326

RADIOMETER

510(k) Summary

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AQT90 FLEX CKMB Test Kit
AQT90 FLEX CKMB CAL Cartridge
AQT90 FLEX LQC Multi-CHECK

Manufacturer

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Signature

Jana S. Hellmann
26 October, 2012

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1. Device names and classifications

- Proprietary name: AQT90 FLEX CKMB Test Kit
  Class II
  Classification name: Creatine phosphokinase/creatine kinase or isoenzymes test system (21 CFR. 862.1215)
  Product code: JHX

- Proprietary name: AQT90 FLEX CKMB CAL Cartridge
  Class II
  Classification name: calibrator, secondary (21 CFR. 862.1150)
  Product code: JIT

- Proprietary name: AQT90 LQC FLEX Multi-CHECK, Levels 1, 2 and 3
  Class I
  Classification name: quality control material (assayed and unassayed) (21 CFR 862.1660)
  Product code: JJY

2. Predicate device

- VIDAS Creatine Kinase MB (CKMB) Assay, 510(k) number K962549
- VIDAS Creatine Kinase MB (CKMB) Calibrators, 510(k) number K962549
- Liquicheck Cardiac Markers Plus Control LT, 510(k) number K050537

3. Device description / test principle

The AQT90 FLEX is a cartridge-based immunoassay, based on time-resolved fluorescence using a europium (Eu) chelate as the fluorescent label. The test receptacles for the assay are 300 µL test cups, which contain the antibodies used for capture of the analyte, and the Eu chelate labeled antibodies used to trace the captured analyte. The sample is added to the test cup together with assay buffer. The cup is then incubated to allow formation of the immuno-complex, and subsequently washed to remove unbound antibodies and sample material. Finally, the cup is exposed to excitation light, and after a delay the emitted light generated by the fluorescent label is measured by single photon counting; this measurement cycle is repeated up to 3,300 times. The total count is then compared to an assay calibration curve to obtain a quantitative measurement of the analyte's concentration in the sample.

This technology uses dried reagents deposited in the test cups and in the calibration adjustment cups – no liquids other than the sample itself together with the assay buffer are required. Total assay time is less than 20 minutes. In summary, the procedure is as follows:

1. Metering of an exact amount of sample and assay buffer and dispensing into a test cup
2. Incubating for 7-15 minutes at 37 °C
3. Washing of the test cup to remove unbound tracer antibodies and sample material
4. Drying the test cup
5. Measuring

4. Device intended use

AQT90 FLEX CKMB Test Kit includes 10 AQT90 FLEX CKMB Test cartridges and one AQT90 FLEX CKMB CAL cartridge. AQT90 FLEX CKMB is an *in vitro* diagnostic assay for the quantitative determination of creatine kinase isoform MB in EDTA or lithium-heparin whole-blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is intended for use as an aid in the diagnosis of myocardial infarction.

AQT90 FLEX CKMB CAL cartridge is for *in vitro* diagnostic use intended for the calibration of the CKMB test on the AQT90 FLEX analyzer by establishing points of reference to estimate CKMB values.

AQT90 FLEX LQC Multi-CHECK, Levels 1-3, is for *in vitro* diagnostic use. For use with the AQT90 FLEX analyzer as a liquid quality control serum (LQC) to monitor the precision of laboratory testing procedures for the analytes listed on the specification insert.

5. Medical device to which substantial equivalence is claimed

The AQT90 FLEX CKMB Test Kit and CKMB CAL cartridges are substantially equivalent in features and characteristics to the VIDAS Creatine Kinase MB (CKMB) Assay and the VIDAS Creatine Kinase MB (CKMB) Calibrator, 510(k) number K962549.

The AQT90 LQC FLEX Multi-CHECK, Levels 1, 2 and 3, is substantially equivalent in features and characteristics to the Liquicheck Cardiac Markers Plus Control LT, 510(k) number K050537.

6. Technological characteristics in comparison to predicate device

Comparison of features for AQT90 FLEX CKMB Test and predicate device

Item	AQT90 FLEX CKMB Test	VIDAS Creatine Kinase MB (CKMB) Assay
Intended use	The AQT90 FLEX CKMB is an *in vitro* diagnostic assay for the quantitative determination of creatine kinase isoform MB in EDTA or lithium-heparin whole-blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is intended for use as an aid in the diagnosis of myocardial infarction. Current international guidelines should always be followed when interpreting CKMB results.	The VIDAS Creatine Kinase MB (CKMB) Assay is for *in vitro* diagnosis and intended for use on the instruments of the VIDAS family (Vitek ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the quantitative determination of creatine kinase MB isoenzyme concentration in human serum or plasma (heparin or EDTA). It is intended for use as an aid in the diagnosis of acute myocardial infarctions.
Test format	Cartridge with 16 test cups, each coated with anti-CKMB capture antibody and containing a separating layer as well as Eu-chelate anti-CKMB tracer. Sample and assay buffer are added to the cup. Assay buffer is located in the Reagent Pack. The pack also receives the discarded cups and liquid waste. After an incubation period, a wash step with assay buffer removes unbound material from the cup, which is subsequently dried. When exposed to an excitation light the bound europium emits a fluorescence, which is measured in cycles of single photon counting. The total count is then compared to an assay calibration curve to obtain a quantitative measurement of the analyte's concentration in the sample.	The VIDAS Creatine Kinase MB (CKMB) assay is an enzyme-linked fluorescent immunoassay that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with mouse monoclonal anti-Creatine Kinase MB antibodies. The VIDAS Creatine Kinase MB (CKMB) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. A prewash step prepares the SPR for the reaction then the sample is transferred into the well containing the sample diluent. Wash steps remove unbound

Item	AQT90 FLEX CKMB Test	VIDAS Creatine Kinase MB (CKMB) Assay
		material. The conjugate is then cycled in and out of the SPR. This step allows the conjugate to attach to the CKMB already fixed to the SPR: thus forming a "sandwich". Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument; it is proportional to the Creatine Kinase MB concentration present in the sample. When the VIDAS Creatine Kinase MB (CKMB) Assay is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.
Traceability	ERM-AD455/IFCC	Not known
Antibodies	Mouse monoclonals for capture and tracer antibody	Mouse monoclonal for capture and goat polyclonal for tracer antibody
Sample type	Human whole blood and plasma	Human serum and plasma
Anticoagulants	EDTA, Li-heparin	EDTA, heparin
Controls	Recommended	Recommended
In-use stability	23 days on-board up to 32 °C	Solid Phase Receptacle not to be left outside 2-8 °C for extended period of time.
Storage temperature	2-8 °C	2-8 °C
Reportable / calibration range	Reportable range 1.5-300 ng/mL (µg/L)	0.8-300 ng/mL

Item	AQT90 FLEX CKMB Test	VIDAS Creatine Kinase MB (CKMB) Assay
Analytical sensitivity	Limit of Quantitation 1 ng/mL (µg/L)	Limit of Detection is 0.8 ng/mL at the 95% level of confidence
Reference range	97.5th percentile for females is 6.9 ng/mL (µg/L), for males 11 ng/mL (µg/L).	99th percentile is 6.8 ng/mL
Imprecision	Across the reportable range, $CV(\%)_{within\text{-}run}$ is ≤ 6.5% for plasma and ≤ 6.0% for whole blood; $CV(\%)_{total}$ is ≤ 8.2% for plasma and ≤ 6.0% for whole blood.	$CV(\%)_{intraassay}$ range is ≤ 6.2%; $CV(\%)_{interassay}$ is ≤ 7.2%; $CV(\%)_{total}$ is ≤ 16.7%
Interference	No interference with CKBB, CKMM, hemoglobin, triglycerides, bilirubin and other endogenous blood components. No interference with any of 52 drugs and solvents tested.	No interference with CKBB and CKMM; no interference with hemoglobin, triglycerides and bilirubin.
Comparison with predicate	Comparison with VIDAS Creatine Kinase MB (CKMB) Assay. Whole blood vs VIDAS: POC Site 1 = 0.93x - 0.2; n = 43; r^2 = 0.99 POC Site 2 = 0.93x + 0.0; n = 46; r^2 = 0.98 POC Site 3 = 0.96x - 0.5; n = 48; r^2 = 0.95 Plasma vs VIDAS: POC Site 1 = 0.94x - 0.3; n = 44; r^2 = 0.99 POC Site 2 = 0.96x + 0.0; n = 46; r^2 = 0.99 POC Site 3 = 0.93x - 0.4; n = 48; r^2 = 0.95	Comparison with Ciba-Corning Magic Lite CK-MB assay, 175 samples in the range 0.8 -300 ng/mL y = 0.83x – 0.66, r = 0.97.

Comparison of features for AQT90 FLEX CKMB CAL and predicate device, the VIDAS Creatine Kinase MB (CKMB) Calibrators

Item	**AQT90 FLEX CKMB CAL**	**VIDAS Creatine Kinase MB (CKMB) Calibrator**
Intended use	The AQT90 FLEX CKMB CAL Cartridge is for *in vitro* diagnostic use and intended for the calibration of the CKMB test on the AQT90 FLEX analyzer by establishing points of reference to estimate CKMB values.	The VIDAS Creatine Kinase MB (CKMB) Calibrator is for *in vitro* diagnostic use and intended for calibration of the VIDAS Creatine Kinase MB (CKMB) assay by verification of the master calibration curve.
Constituents	Each CAL Cartridge contains eight analyte-specific background cups and eight cups with added antigen.	1 x 3 mL (lyophilized)
Calibration adjustment interval	Once per lot of AQT90 FLEX CKMB Test cartridges and as often as required by relevant regulations.	Upon receipt of new lot of assay reagents and every 14 days thereafter.
In-use stability	24 hours on-board up to 32 °C	24 hours at 2-8 °C when reconstituted; until expiry date at 25±6 °C when reconstituted
Storage temperature	2-8 °C	2-8 °C or -25±6 °C when reconstituted

Comparison of features for AQT90 FLEX LQC Multi-CHECK and predicate device, the Liquicheck Cardiac Markers Plus Control LT

Item	**AQT90 LQC FLEX Multi-CHECK**	**Liquicheck Cardiac Markers Plus Control LT**
Intended use	The AQT90 FLEX LQC Multi-CHECK, Levels 1-3, is for *in vitro* diagnostic use. For use with the AQT90 FLEX analyzer as a liquid quality control serum (LQC) to monitor the precision of laboratory testing procedures for the analytes listed on the specification insert.	Liquicheck Cardiac Markers Plus Control LT is intended for use as quality control serum to monitor the precision of laboratory testing procedures listing in the package insert.
Analytes contained	CKMB, Myoglobin	B-type Natriuretic Peptide (BNP), Creatine Kinase (Total), C-Reactive Protein (CRP), Homocysteine, Digitoxin, N-terminal pro-B-type Natriuretic Peptide (NT-proBNP), CKMB, Myoglobin, Troponin I, Troponin T.
Matrix	Human serum	Human serum
Storage temperature	≤ -18 °C until expiration date; shelf life claim is 12 months.	–20 °C to –70 °C until expiration date.
In-use stability	4 days if stored unused at 2-8 °C; 2 hours if stored unused at room temperature 15-32 °C.	20 days at 2-8 °C

Summary of clinical performance data

The AQT90 FLEX CKMB assay (y) was compared to the predicate device, the VIDAS Creatine Kinase MB (CKMB) Assay (x) using lithium-heparin plasma and whole blood samples in the range of 2.1 - 217 ng/mL (µg/L) and 1.5 - 277 ng/mL (µg/L), respectively. The relationship between the two methods was determined by Passing-Bablok regression. The regression lines and correlation coefficients for whole blood samples were for POC Site 1 = 0.93x - 0.2; n = 43; r^2 = 0.99, for POC Site 2 = 0.93x + 0.0; n = 46; r^2 = 0.98 and for POC Site 3 = 0.96x - 0.5; n = 48; r^2 = 0.95. For plasma samples the regressions lines and correlation coefficients were for POC Site 1 = 0.94x - 0.3; n = 44; r^2 = 0.99, for POC Site 2 = 0.96x + 0.0; n = 46; r^2 = 0.99 and for POC Site 3 = 0.93x - 0.4; n = 48; r^2 = 0.95.

7. Conclusion

The products listed in the table are substantially equivalent based on their indications for use and performance characteristics.

New Device	Predicate Device
AQT90 FLEX CKMB Test Kit. Class II. Classification name: Creatine phosphokinase/creatine kinase or isoenzymes test system (21 CFR. 862.1215), product code JHX	VIDAS Creatine Kinase MB (CKMB) Assay, 510(k) number K962549
AQT90 FLEX CKMB CAL Cartridge. Class II. Classification name: calibrator, secondary, (21 CFR. 862.1150), product code JIT	VIDAS Creatine Kinase MB (CKMB) Calibrators, 510(k) number K042924
AQT90 FLEX LQC Multi-CHECK, Levels 1, 2 and 3. Class I. Classification name: quality control material (assayed and unassayed) (21 CFR 862.1660), product code JJY	Liquicheck Cardiac Markers Plus Control LT, 510(k) number K050537

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 21, 2012

Radiometer Medical ApS
c/o Gitte Friis
Director, Regulatory Affairs
Aakandejev 21
Bronshoj, Denmark DK 2700

Re: k120326
Trade/Device Name: AQT90 FLEX CKMB Test Kit; AQT90 FLEX CKMB CAL Cartridge; AQT90 FLEX LQC Multi-CHECK, Levels 1-3
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHX, JIT, JJY
Dated: October 26, 2012
Received: October 31, 2012

Dear Gitte Friis:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120326

Device Name: AQT90 FLEX CKMB Test Kit
AQT90 FLEX CKMB CAL Cartridge
AQT90 FLEX LQC Multi-CHECK, Levels 1-3

Indications for Use:

AQT90 FLEX CKMB Test is an *in vitro* diagnostic assay for the quantitative determination of creatine kinase isoform MB in EDTA or lithium-heparin whole blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is intended for use as an aid in the diagnosis of myocardial infarction.

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Prescription Use __x_____ AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) k120326