RADIOMETER MEDICAL APS
PER PAPE THOMSEN
REGULATORY AFFAIRS SPECIALIST
AKANDEVEJ 21
2700 BROENSHOEJ, DENMARK

Re: K163462
Trade/Device Name: AQT90 FLEX CKMB Test Kit
AQT90 FLEX Myo Test Kit
AQT90 FLEX
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: II
Product Code: JHX, DDR, KHO
Dated: September 15, 2017
Received: September 18, 2017

Dear Per Pape Thomsen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

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

The 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.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)
- Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
Indications for Use

The Myo Test is an in vitro diagnostic assay for the quantitative determination of myoglobin 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 rapid diagnosis of heart disease, for example, acute myocardial infarction.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRAS Staff@fda.hhs.gov

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Indications for Use

For in vitro diagnostic use.
The AQT90 FLEX analyzer is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate the concentrations of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point-of-care and laboratory settings.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)
- Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K163462

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter and Contact Information

Submitter
Company Name: Radiometer Medical ApS
ER Number: 3002807968
Address: Aakandevej 21
2700 Broenshoej
Denmark
Phone: +45 3827 3827
Fax: +45 3827 2727

Contact Person
Name: Per Pape Thomsen
Function: Regulatory Affairs Specialist
E-mail: per.pape.thomsen@radiometer.dk
Phone: +45 3827 3304
Fax: +45 3827 2727
Date prepared: September 18, 2017

2.a Device Information

Device Name: AQT90 FLEX Myo Test Kit
Regulation Name: Myoglobin Immulogical Test System
Product Code: DDR
Regulation Section: 21 CFR 866.5680
Classification: Class II
Classification Panel: Immunology (82)

Device Name: AQT90 FLEX CKMB Test Kit
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Product Code: JHX
Regulation Section: 21 CFR 862.1215
Classification: Class II
Classification Panel: Clinical Chemistry (75)

Device Name: AQT90 FLEX
Regulation Name: Fluorometer for clinical use
Product Code: KHO
Regulation Section: 21 CFR 862.2560
Classification: Class I
Classification Panel: Clinical Chemistry (75)
2.b Device Description

The AQT90 FLEX is a cartridge-based immunoassay analyzer, based on time-resolved fluorescence using a europium (Eu) chelate as the fluorescent label. The test receptacles for the assay are 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. 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. 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 test cup
3. Washing of the test cup to remove unbound tracer antibodies and sample material
4. Drying the test cup
5. Measuring

2.c Purpose of submission

The purpose of this submission is to seek clearance for modifications to the existing AQT90 FLEX system devices.

The modifications implemented on the AQT90 FLEX System are outlined below:

- Three separate analyzer manuals are combined into one manual, which is updated to include changes in analyzer functionality
- System Clean is updated to implement semi-automated System Clean using two new accessories; Blank Cartridge and Cleaning Solution Tubes
- Algorithm used to determine hematocrit value is updated
- Needle used in cup wash is shortened
- Flash lamp in detection system is changed to a new flash lamp
- The filter, which is located in the liquid pathway after the cup washing step, is removed
- Test cartridge and CAL cartridge foil is pre-laser cut on one side of the foil instead of both sides
- Recombinant streptavidin from a new supplier which is chemically identical to the old native streptavidin. Streptavidin is used to bind capture antibody onto the cup surface

These modifications include changes which potentially could impact Myo Test and CKMB Test performance and instructions for use.

In addition to the modifications listed above the AQT90 FLEX analyzer has been maintained via software updates. Also minor updates to consumable inserts have been introduced.
3. Indications for Use

**AQT90 FLEX**
For in vitro diagnostic use.
The AQT90 FLEX analyzer is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate the concentrations of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point-of-care and laboratory settings.

**AQT90 FLEX Myo Test Kit**
The Myo Test is an in vitro diagnostic assay for the quantitative determination of myoglobin 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 rapid diagnosis of heart disease, for example, acute myocardial infarction.

**AQT90 FLEX CKMB Test Kit**
The 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.

4. Substantial Equivalence

The AQT90 FLEX System devices are substantial equivalent in intended use, fundamental scientific technology, and characteristics to the predicates (K112161, K120326).

### Predicate devices

<table>
<thead>
<tr>
<th>Predicate name</th>
<th>Device Manufacturer</th>
<th>510(k) number</th>
</tr>
</thead>
<tbody>
<tr>
<td>AQT90 FLEX Myo Test kit</td>
<td>Radiometer Medical Aps</td>
<td>K112161</td>
</tr>
<tr>
<td>AQT90 FLEX CKMB Test Kit</td>
<td>Radiometer Medical Aps</td>
<td>K120326</td>
</tr>
<tr>
<td>AQT90 FLEX (analyzer)</td>
<td>Radiometer Medical Aps</td>
<td>K112161</td>
</tr>
</tbody>
</table>

### Similarities and Differences

The updated AQT90 FLEX System devices are compared to the predicates in the tables below.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate device (K112161)</th>
<th>AQT90 FLEX Myo Test kit (updated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td><strong>AQT90 FLEX Myo Test</strong> is an <em>in vitro</em> diagnostic assay for the quantitative determination of myoglobin in EDTA or lithium-heparin whole blood or plasma specimens on the AQT90 FLEX analyzer in point of care and laboratory settings. It is indicated for use as an aid in the rapid diagnosis of heart disease, e.g. acute myocardial infarction.</td>
<td>Same</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate device (K112161) AQT90 FLEX Myo Test kit</th>
<th>AQT90 FLEX Myo Test kit (updated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle</td>
<td>Quantitative time-resolved fluorimetric one-step sandwich immunoassay.</td>
<td>Same</td>
</tr>
<tr>
<td>Traceability</td>
<td>Scripps M0725</td>
<td>Same</td>
</tr>
<tr>
<td>Reportable range</td>
<td>20 to 900</td>
<td>Same</td>
</tr>
<tr>
<td>Cartridge foil</td>
<td>Test cartridge is pre-laser cut on both sides of the foil.</td>
<td>Test cartridge is pre-laser cut on one side of the foil.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate device (K120326) AQT90 FLEX CKMB Test Kit</th>
<th>AQT90 FLEX CKMB Test Kit (updated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td>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.</td>
<td>Same</td>
</tr>
<tr>
<td>Principle</td>
<td>Quantitative time-resolved fluorimetric one-step sandwich immunoassay</td>
<td>Same</td>
</tr>
<tr>
<td>Traceability</td>
<td>ERM-AD455/IFCC</td>
<td>Same</td>
</tr>
<tr>
<td>Reportable range</td>
<td>1.5 to 300</td>
<td>Same</td>
</tr>
<tr>
<td>Cartridge foil</td>
<td>Test cartridge is pre-laser cut on both sides of the foil.</td>
<td>Test cartridge is pre-laser cut on one side of the foil.</td>
</tr>
</tbody>
</table>
### Characteristic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate device (K112161) AQT90 FLEX (analyzer)</th>
<th>AQT90 FLEX (analyzer) (updated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td><strong>AQT90 FLEX analyzer</strong> is for <em>in vitro</em> diagnostic use. The AQT90 FLEX analyzer is an immunoassay instrument based on the quantitative determination of time-resolved fluorescence to estimate the concentrations of clinically relevant markers on whole-blood and plasma specimens to which a relevant anticoagulant has been added. It is intended for use in point of care and laboratory settings.</td>
<td>Same</td>
</tr>
<tr>
<td>System cleaning</td>
<td>System cleaning using customer prepared cleaning sample and test cup.</td>
<td>Semi-automated system cleaning using cleaning tube from Cleaning Solution Tubes and blank cup from Blank Cartridge.</td>
</tr>
</tbody>
</table>

### 5. Performance Characteristics

No performance data are affected by the introduction of the modifications to the AQT90 FLEX system. The existing performance data still apply.

To confirm that the modifications have no effect on performance the following studies for Myo test and CKMB test were conducted: Linearity, LoB/LoD/LoQ, Method Comparison, Matrix comparison, Precision.

#### 5.1 Myo Test

**Myo Linearity**

The study was designed according to CLSI guideline EP06-A. Low and High concentration lithium heparin whole blood and lithium heparin plasma samples were used to prepare a linearity series of 11 sample levels. The samples were measured with ten replicates in random order using one Test Kit lot and one analyzer during one day. The linear, quadratic and cubic regression models were fit to the data weighted by 1/variance. The statistical significance of each fit parameter was determined and, where appropriate, the degree of non-linearity was calculated.

The degree of non-linearity was determined to be within 10 % throughout the reportable range (20 – 900 ng/mL) for whole blood and plasma.
**Myo LoB/LoD/LoQ**

The study was designed according to CLSI guideline EP17-A2.

The determination of LoB was performed by measuring four blank samples with five replicates on three days using two Test Kit lots and two AQT90 FLEX analyzers. The total number of measurements per Test Kit lot across all samples and days was 60.

The determination of LoD and LoQ was performed with lithium heparin whole blood and lithium heparin plasma. Ten samples per matrix were measured using two Test Kit lots and two AQT90 FLEX analyzers. The LoB estimate, determined by nonparametric method, and the SD_{within-lab} of the lowest concentration samples were used to determine the LoD. A power function was fit to the concentration versus CV_{within-lab} plot using data from all samples. The intersection of this fit and 10 % CV_{within-lab} was used to determine LoQ.

The results of the studies support the claimed LoB, LoD, LoQ summarized in the table below:

<table>
<thead>
<tr>
<th>Analytical sensitivity</th>
<th>Myo ng/mL (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of blank (LoB)</td>
<td>0.5</td>
</tr>
<tr>
<td>Limit of detection (LoD)</td>
<td>1</td>
</tr>
<tr>
<td>Limit of quantitation (LoQ)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Myo Method Comparison**

The study was designed according to CLSI guideline EP09-A3. Lithium heparin plasma samples in the range 26 - 897 ng/mL were measured at one internal test site across four AQT90 FLEX analyzers. One Myo Test Kit lot was used. The Myoglobin measured on the modified AQT90 FLEX analyzer (y) was compared to the Myoglobin measured on the predicate (x).

The Passing-Bablok regression equation for plasma was found to be: \( y = 1.01x - 0.14 \) (n=103; \( r^2 = 1.0 \))

**Myo Matrix Comparison**

The study was designed according to CLSI guideline EP09-A3. The study was conducted at three hospital laboratory sites on one AQT90 FLEX analyzer per site. One Myo Test Kit lot was used across sites. Paired lithium heparin and EDTA specimens were measured across the reportable range of 20 - 900 ng/mL.

The equivalence between the measurement procedures on the AQT90 FLEX analyzer with lithium heparin whole blood, lithium heparin plasma, EDTA whole blood, and EDTA plasma samples were determined. No matrix effect differences were seen caused by differences in specimen types (whole blood vs. plasma) or anticoagulants (lithium heparin vs. EDTA). The four anticoagulant matrix combinations can be used interchangeably.

The Passing-Bablok regression equations were found to be:

- Lithium heparin plasma (y) = 0.99 Lithium heparin whole blood (x) - 1.0 (n=125; \( r^2 = 1.0 \))
- EDTA plasma (y) = 0.96 EDTA whole blood (x) - 1.4 (n=125; \( r^2 = 1.0 \))
- EDTA whole blood (y) = 1.01 Lithium heparin whole blood (x) + 0.8 (n=127; \( r^2 = 1.0 \))
- EDTA plasma (y) = 0.99 Lithium heparin plasma (x) + 0.2 (n=124; \( r^2 = 1.0 \))
- EDTA whole blood (y) = 1.03 Lithium heparin plasma (x) + 1.6 (n=125; \( r^2 = 1.0 \))
**Myo Precision**

The study was designed according to CLSI guideline EP05-A3.

In the whole blood precision study three lithium heparin whole blood samples were measured, each within one day five times (runs) with five replicates using one analyzer and one Test Kit lot.

Myo whole blood precision results; L1: diluted native specimen, L2: native specimen, L3: native specimen spiked with antigen.

<table>
<thead>
<tr>
<th>Sample description</th>
<th>Mean value (ng/mL)</th>
<th>n</th>
<th>Repeatability</th>
<th>Between-Run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
<td>SD (ng/mL)</td>
</tr>
<tr>
<td>L1</td>
<td>57</td>
<td>25</td>
<td>1.30</td>
<td>2.3</td>
<td>0.00</td>
</tr>
<tr>
<td>L2</td>
<td>92</td>
<td>25</td>
<td>2.57</td>
<td>2.8</td>
<td>0.93</td>
</tr>
<tr>
<td>L3</td>
<td>622</td>
<td>25</td>
<td>14.1</td>
<td>2.3</td>
<td>4.94</td>
</tr>
</tbody>
</table>

In the plasma precision study three lithium heparin plasma pools were measured across 20 test days, twice a day with two replicates, using one analyzer and one Test Kit lot.

Myo plasma precision results; L1: native specimen pool, L2: native specimen pool, L3: native specimen pool spiked with antigen.

<table>
<thead>
<tr>
<th>Sample description</th>
<th>Mean value (ng/mL)</th>
<th>n</th>
<th>Repeatability</th>
<th>Between-Run</th>
<th>Between-Day</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
</tr>
<tr>
<td>L1</td>
<td>53</td>
<td>80</td>
<td>1.0</td>
<td>2.0</td>
<td>0.47</td>
<td>0.9</td>
</tr>
<tr>
<td>L2</td>
<td>95</td>
<td>80</td>
<td>1.9</td>
<td>2.0</td>
<td>0.00</td>
<td>0.0</td>
</tr>
<tr>
<td>L3</td>
<td>586</td>
<td>80</td>
<td>13</td>
<td>2.2</td>
<td>0.00</td>
<td>0.0</td>
</tr>
</tbody>
</table>

### 5.2 CKMB Test

**CKMB Linearity**

The study was designed according to CLSI guideline EP06-A. Low and High concentration lithium heparin whole blood and lithium heparin plasma samples were used to prepare a linearity series of 11 sample levels. The samples were measured with ten replicates in random order using one Test Kit lot and one analyzer during one day. The linear, quadratic and cubic regression models were fit to the data weighted by 1/variance. The statistical significance of each fit parameter was determined and, where appropriate, the degree of non-linearity was calculated.

The degree of non-linearity was determined to be within 10 % throughout the reportable range (1.5 – 300 ng/mL) for whole blood and plasma.

**CKMB LoB/LoD/LoQ**

The study was designed according to CLSI guideline EP17-A2.

The determination of LoB was performed by measuring four blank samples with five replicates on three days using two Test Kit lots and two AQT90 FLEX analyzers. The total number of measurements per Test Kit lot across all samples and days was 60.
The determination of LoD and LoQ was performed with lithium heparin whole blood and lithium heparin plasma. Ten samples per matrix were measured using two Test Kit lots and two AQT90 FLEX analyzers. The LoB estimate, determined by nonparametric method, and the SD\textsubscript{within-lab} of the lowest concentration samples were used to determine the LoD. A power function was fit to the concentration versus CV\textsubscript{within-lab} plot using data from all samples. The intersection of this fit and 20 % CV\textsubscript{within-lab} was used to determine LoQ.

The results of the studies support the claimed LoB, LoD, LoQ summarized in the table below:

<table>
<thead>
<tr>
<th>Analytical sensitivity</th>
<th>CKMB ng/mL (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of blank (LoB)</td>
<td>0.5</td>
</tr>
<tr>
<td>Limit of detection (LoD)</td>
<td>1</td>
</tr>
<tr>
<td>Limit of quantitation (LoQ)</td>
<td>1</td>
</tr>
</tbody>
</table>

**CKMB Method Comparison**

The study was designed according to CLSI guideline EP09-A3. Lithium heparin plasma samples in the range 1.5 - 296 ng/mL were measured at one internal test site across four AQT90 FLEX analyzers. One CKMB Test Kit lot was used. The CKMB measured on the modified AQT90 FLEX analyzer (y) was compared to the CKMB measured on the predicate (x).

The Passing-Bablok regression equation for plasma was found to be: \( y = 0.99 x - 0.18 \) (n= 107; \( r^2 = 1.0 \))

**CKMB Matrix Comparison**

The study was designed according to CLSI guideline EP09-A3. The study was conducted at three hospital laboratory sites on one AQT90 FLEX analyzer per site. One CKMB Test Kit lot was used across sites. Paired lithium heparin and EDTA specimens were measured across the reportable range of 1.5 - 300 ng/mL.

The equivalence between the measurement procedures on the AQT90 FLEX analyzer with lithium heparin whole blood, lithium heparin plasma, EDTA whole blood, and EDTA plasma samples were determined. No matrix effect differences were seen caused by differences in specimen types (whole blood vs. plasma) or anticoagulants (lithium heparin vs. EDTA). The four anticoagulant matrix combinations can be used interchangeably.

The Passing-Bablok regression equations were found to be:

- Lithium heparin plasma \( y = 0.99 \) Lithium heparin whole blood \( x \) + 0.01 (n= 106; \( r^2 = 1.0 \))
- EDTA plasma \( y = 0.99 \) EDTA whole blood \( x \) - 0.02 (n= 104; \( r^2 = 1.0 \))
- EDTA whole blood \( y = 1.02 \) Lithium heparin whole blood \( x \) + 0.01 (n= 103; \( r^2 = 1.0 \))
- EDTA plasma \( y = 1.01 \) Lithium heparin plasma \( x \) - 0.04 (n= 101; \( r^2 = 1.0 \))
- EDTA whole blood \( y = 1.03 \) Lithium heparin plasma \( x \) - 0.02 (n= 104; \( r^2 = 1.0 \))

**CKMB Precision**

The study was designed according to CLSI guideline EP05-A3.

In the whole blood precision study three lithium heparin whole blood samples were measured, each within one day five times (runs) with five replicates using one analyzer and one Test Kit lot.
CKMB whole blood precision results; L1: diluted native specimen, L2: native specimen spiked with antigen, L3: native specimen spiked with antigen.

<table>
<thead>
<tr>
<th>Sample description</th>
<th>Mean value (ng/mL)</th>
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<th>Repeatability</th>
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<td></td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
<td>SD (ng/mL)</td>
</tr>
<tr>
<td>L1</td>
<td>2.6</td>
<td>0.13</td>
<td>4.8</td>
<td>0.00</td>
<td>0.13</td>
</tr>
<tr>
<td>L2</td>
<td>14</td>
<td>0.50</td>
<td>3.5</td>
<td>0.49</td>
<td>0.70</td>
</tr>
<tr>
<td>L3</td>
<td>204</td>
<td>6.9</td>
<td>3.4</td>
<td>0.00</td>
<td>6.9</td>
</tr>
</tbody>
</table>

In the plasma precision study three lithium heparin plasma pools were measured across 20 test days, twice a day with two replicates, using one analyzer and one Test Kit lot.

CKMB plasma precision results; L1: native specimen pool, L2: native specimen pool spiked with high patient specimen, L3: native specimen pool spiked with antigen.

<table>
<thead>
<tr>
<th>Sample description</th>
<th>Mean value (ng/mL)</th>
<th>n</th>
<th>Repeatability</th>
<th>Between-Run</th>
<th>Between-Day</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
<td>SD (ng/mL)</td>
<td>CV (%)</td>
</tr>
<tr>
<td>L1</td>
<td>2.3</td>
<td>0.080</td>
<td>3.5</td>
<td>0.026</td>
<td>0.00</td>
<td>0.084</td>
</tr>
<tr>
<td>L2</td>
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<td>0.21</td>
<td>2.5</td>
<td>0.083</td>
<td>0.088</td>
<td>0.24</td>
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<tr>
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<td>209</td>
<td>3.9</td>
<td>1.9</td>
<td>1.4</td>
<td>0.7</td>
<td>1.8</td>
</tr>
</tbody>
</table>

6. Conclusion
Based on the substantial equivalence comparison and the results of the conducted performance evaluations it has been concluded that the AQT90 FLEX System devices is as safe and effective as the predicate devices.