



Food and Drug Administration  
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AALTO SCIENTIFIC, LTD.  
ROBERT BURDA  
REGULATORY AFFAIRS DIRECTOR  
230 TECHNOLOGY PARKWAY  
EATONTON GA 30642

August 10, 2016

Re: K161874

Trade/Device Name: Audit® MicroControls™ Linearity Drop LQ Blood Glucose  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: I, Reserved  
Product Code: JJX  
Dated: July 7, 2016  
Received: July 8, 2016

Dear Robert Burda:

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,

  
**Katherine Serrano -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

510(k) Number (if known)  
K161874

Device Name  
Audit® MicroControls™ Linearity DROP LQ Blood Glucose

### Indications for Use (Describe)

The Audit® MicroControls™ Linearity DROP LQ Blood Glucose is intended to simulate human patient samples for use as assayed quality control material, determining linearity, calibration verification, and the verification of reportable range for the glucose analyte.

The Audit® MicroControls™ Linearity DROP LQ Blood Glucose is for In Vitro Diagnostic use only.

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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## 510(k) Summary K161874

### A. Submitter

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#### Contact Person

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#### Date of Summary Preparation

August 05, 2016

### B. Device Identification

Product Trade Name: Audit<sup>®</sup> MicroControls<sup>™</sup> Linearity DROP LQ Blood Glucose  
Common Name: Single (Specified) Analyte Controls (Assayed and Unassayed)  
Review Panel: Clinical Chemistry  
Device Classification: Class I, Reserved  
Product Code: JJX  
Regulation Number: 21CFR862.1660

### C. Device to Which Substantial Equivalence is Claimed

K130762: Audit<sup>®</sup> MicroCV<sup>™</sup> Therapeutic Drug (TDM) Linearity Set

### D. Intended Use

The Audit<sup>®</sup> MicroControls<sup>™</sup> Linearity DROP LQ Blood Glucose is intended to simulate human patient samples for use as assayed quality control material, determining linearity, calibration verification, and the verification of reportable range for the glucose analyte.

The Audit<sup>®</sup> MicroControls<sup>™</sup> Linearity DROP LQ Blood Glucose is for In Vitro Diagnostic use only.

### E. Technical Characteristics Compared to Predicate Device

<b>Characteristics</b>	(New Device) Audit® MicroControls™ Linearity DROP LQ Blood Glucose	(Predicate Device, K130762) Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set
<b>Intended Use</b>	<p>The Audit® MicroControls™ Linearity DROP LQ Blood Glucose is intended to simulate human patient samples for use as assayed quality control material, determining linearity, calibration verification, and the verification of reportable range for the glucose analyte.</p> <p>The Audit® MicroControls™ Linearity DROP LQ Blood Glucose is for In Vitro Diagnostic use only.</p>	<p>The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains: Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbital, Phenytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid and Vancomycin. These five levels demonstrate a linear relationship to each other for their respective analytes. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbital, Phenytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid and Vancomycin. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™</p>

		Therapeutic Drug (TDM) Linearity Set should not be used for calibration or standardization of the Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbital, Phenytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid and Vancomycin assays. The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is "For In Vitro Diagnostic Use Only".
<b>Matrix</b>	Human Serum	Human Serum
<b>Type of Analytes</b>	Clinical Chemistry	Clinical Chemistry
<b>Form</b>	Liquid	Freeze-dried powder
<b>Storage</b>	2-8°C	2-8°C
<b>Shelf Life</b>	2 years at 2-8°C	2 years at 2-8°C
<b>Open Vial Stability</b>	7 days at 2-8°C	7 days at 2-8°C
<b>Sterile</b>	No	No
<b>Analytes</b>	Glucose	Acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lithium, phenobarbital, phenytoin, quinidine, salicylate, theophylline, tobramycin, valproic acid, and vancomycin.

#### F. Device Description

The Audit® MicroControls™ Linearity DROP LQ Blood Glucose is an in-vitro diagnostic device consisting of sets of 5 levels of liquid, linearity material and additives in human based serum. The product contains the following analyte: glucose. Each set consists of 5 levels labeled Level A, B, C, D and E. Each level has a fill size of 1ml. Materials of human origin used in the manufacture of this linearity set have been tested using FDA approved methods and are found to be non-reactive for HbsAg and antibodies to HCV and HIV-1/2.

#### G. Value Assignment/Linearity

The mean and expected range for each method shall be presented in each lot specific insert of Audit<sup>®</sup> MicroControls<sup>™</sup> Linearity DROP LQ Blood Glucose. The indicated values shall be derived from analysis of vials representative of the entire lot. Analyte value assignment for Level A through Level E was performed on Roche Cobas for the blood glucose analyte using the corresponding reagent. The analyte was measured multiple times. The mean value of the analyte was used to establish a target concentration value at each level. All supporting data is retained on file at Aalto Scientific, Ltd.

## H. Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Audit<sup>®</sup> MicroControls<sup>™</sup> Linearity DROP LQ Blood Glucose.

### Shelf Life-Accelerated Stability

Accelerated stability studies were conducted to establish the shelf life stability claims. All supporting data is retained on file at Aalto Scientific, Ltd. Acceptance criteria were met to support the product claims as follows:

*Shelf Life:* 2 years, when stored unopened at 2-8<sup>o</sup> C.

### Shelf Life-Real Time Stability

Real time studies are ongoing to support the shelf life of this product.

### Open Vial Stability

Real time stability studies were conducted to establish the open vial stability claims. All supporting data is retained on file at Aalto Scientific, Ltd. Acceptance criteria were met to support the product claims as follows:

*Open Vial Stability:* Once a vial has been opened, the product will be stable for 7 days when stored tightly capped at 2-8<sup>o</sup> C.

## I. Expected Values

Analyte value assignment was performed for Audit<sup>®</sup> MicroControls<sup>™</sup> Linearity DROP LQ Blood Glucose using the corresponding reagents for blood glucose. The analyte was measured multiple times and the mean value was used to establish target concentration values at each level. The target ranges are shown below.

The expected range of the mean is provided to assist the laboratory until it has established its own mean and standard deviation. The indicated mean and expected range (target range) of the mean is provided to serve only as a guide in assessing the performance of the test method in laboratories.

Approximate target values for glucose are given in the table below. Lot-specific target values may differ after value assignment.

Glucose (mg/dL)/Roche Cobas c501									
Level A		Level B		Level C		Level D		Level E	
Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range	Target value	Target Range
10.7	8.5-12.8	231.0	184.8-277.2	454.7	363.7-545.6	661.5	529.2-793.8	858.0	686.4-1029.6

Levels B, C and D produced according to the following dilution scheme:

$$\text{Level B} = 0.75(\text{Level A}) + 0.25(\text{Level E})$$

$$\text{Level C} = 0.5(\text{Level A}) + 0.5(\text{Level E})$$

$$\text{Level D} = 0.25(\text{Level A}) + 0.75(\text{Level E})$$

#### J. Traceability

Materials are obtained from internally qualified vendors and are subject to an internal quality control process. Raw material information is retained on file at Aalto Scientific, Ltd.

#### K. Conclusions

Based upon the purpose of the device, the descriptions and labeling of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.