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

Re: K163629
Trade/Device Name: Audit® MicroControls™ Linearity FD Tumor Markers II
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: December 21, 2016
Received: January 11, 2017

Dear Mr. 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,

Kelly Oliner -S

For
Leonthena Carrington, MBA, MS, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health]
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known)
K163629

Device Name
Audit® MicroControls™ Linearity FD Tumor Markers II

Indications for Use (Describe)
The Audit® MicroControls™ Linearity FD Tumor Markers II 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 HE4 and HER2 analytes.

The Audit® MicroControls™ Linearity FD Tumor Markers II 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.

*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:

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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.”
510(k) Summary: K163629

A. Submitter

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Contact Person

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Regulatory Affairs Director
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Email: rburda@aaltoscientific.com

Date of Summary Preparation

March 06, 2017

B. Device Identification

Product Trade Name: Audit® MicroControls™ Linearity FD Tumor Markers II
Common Name: Multi-Analyte Controls (Assayed and Unassayed)
Review Panel: Clinical Chemistry
Device Classification: Class I, Reserved
Product Code: JJY
Regulation Number: 21CFR862.1660

C. Device to Which Substantial Equivalence is Claimed

K130762: Audit® MicroCV ™ Therapeutic Drug (TDM) Linearity Set

D. Intended Use

The Audit® MicroControls™ Linearity FD Tumor Markers II 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 HE4 and HER2 analytes.

The Audit® MicroControls™ Linearity FD Tumor Markers II is for In Vitro Diagnostic use only.
E. Technical Characteristics Compared to Predicate Device

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>(New Device, K163629) Audit® MicroControls™ Linearity FD Tumor Markers II</th>
<th>(Predicate Device, K130762) Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>The Audit® MicroControls™ Linearity FD Tumor Markers II 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 HE4 and HER2 analytes. The Audit® MicroControls™ Linearity FD Tumor Markers II is for In Vitro Diagnostic use only.</td>
<td>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...</td>
</tr>
</tbody>
</table>
**F. Device Description**

The Audit® MicroControls™ Linearity FD Tumor Markers II is an in-vitro diagnostic device consisting of sets of 5 levels of freeze-dried, linearity material and additives in human based serum. The product contains the following analytes: HE4 and HER2. 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.

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<table>
<thead>
<tr>
<th>Matrix</th>
<th>Human Serum</th>
<th>Human Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Analytes</td>
<td>Clinical Chemistry</td>
<td>Clinical Chemistry</td>
</tr>
<tr>
<td>Form</td>
<td>Freeze-dried powder</td>
<td>Freeze-dried powder</td>
</tr>
<tr>
<td>Storage</td>
<td>2-8°C</td>
<td>2-8°C</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>2 years at 2-8°C</td>
<td>2 years at 2-8°C</td>
</tr>
<tr>
<td>Open Vial Stability</td>
<td>7 days at 2-8°C</td>
<td>7 days at 2-8°C</td>
</tr>
<tr>
<td>Sterile</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Analytes</td>
<td>HE4, HER2</td>
<td>Acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lithium, phenobarbital, phenytoin, quinidine, salicylate, theophylline, tobramycin, valproic acid, and vancomycin.</td>
</tr>
</tbody>
</table>
G. Value Assignment/Linearity

The mean and expected range for each method shall be presented in each lot specific insert of Audit® MicroControls™ Linearity FD Tumor Markers II. 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 Siemens Centaur XP for the HER2 analyte and the Roche Cobas e411 for the HE4 analyte using the corresponding reagents. The analytes were measured multiple times. The mean value of each 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® MicroControls™ Linearity FD Tumor Markers II.

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 2-8º 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 2-8º C.

I. Expected Values

Analyte value assignment was performed for Audit® MicroControls™ Linearity FD Tumor Markers II using the corresponding reagents for HE4 and HER2. Each 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 HE4 and HER2 are given in the table below. Lot-specific target values may differ after value assignment.

### HE4/Roche Cobas e411 (pmol/L)

<table>
<thead>
<tr>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level A</td>
<td>20.5</td>
<td>16.4- 30.6</td>
<td>Level B</td>
<td>24.6</td>
<td>30.5- 45.7</td>
<td>Level C</td>
<td>380.6</td>
<td>273.9- 516.7</td>
<td>Level D</td>
<td>627.1</td>
<td>497.2- 880.7</td>
</tr>
<tr>
<td>Level A</td>
<td>20.5</td>
<td>16.4- 30.6</td>
<td>Level B</td>
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</tr>
</tbody>
</table>

### HER2/Siemens Centaur XP (ng/ml)

<table>
<thead>
<tr>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
<th>Level</th>
<th>Target Value</th>
<th>Target Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level A</td>
<td>5.1</td>
<td>4.1- 6.1</td>
<td>Level B</td>
<td>74.0</td>
<td>59.2- 94.6</td>
<td>Level C</td>
<td>88.8</td>
<td>69.2- 108.9</td>
<td>Level D</td>
<td>146.0</td>
<td>116.8- 175.2</td>
</tr>
<tr>
<td>Level A</td>
<td>5.1</td>
<td>4.1- 6.1</td>
<td>Level B</td>
<td>74.0</td>
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<td>Level C</td>
<td>88.8</td>
<td>69.2- 108.9</td>
<td>Level D</td>
<td>146.0</td>
<td>116.8- 175.2</td>
</tr>
</tbody>
</table>

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

Level B = 0.75(Level A) + 0.25(Level E)

Level C = 0.5(Level A) + 0.5(Level E)

Level D = 0.25(Level A) + 0.75(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.