**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 16, 2015

Aalto Scientific Ltd.
c/o Mr. Robert Burda
Regulatory Affairs Manager
1959 Kellogg Avenue
Carlsbad, CA 92008

Re: k143573
Trade/Device Name: Audit® MicroControls™ FD Linearity Tumor Markers II
Regulation Number: 21 §CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: December 12, 2014
Received: December 17, 2014

Dear Mr. 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 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 Part 801), 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" (21CFR 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,

Leonthena R. Carrington -A

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143573

Device Name
Audit® MicroControls™ Linearity FD Tumor Markers II

Indications for Use *(Describe)*
The Linearity FD Tumor Markers II is an assayed quality control material intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), Prostate-specific antigen-total (PSA), Carbonic Anhydrase-125 (CA-125), Carbonic Anhydrase 19-9 (CA19-9), Carbonic Anhydrase 27-29 (CA27-29)/(BR), free-PSA (fPSA), and Carbonic Anhydrase 15-3 (CA15-3).

The 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@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."*

## Aalto Scientific Ltd.

# 510(k) Summary

### 510(k) Summary - Audit® MicroControls™ Linearity FD Tumor Markers II

**Introduction:** According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

**The assigned 510(k) number: k143573**

**A. Submitter**

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
Telephone: (760) 431-7922
Fax: (760) 431-6942

Contact Person

Robert Burda
Regulatory Affairs Manager
Telephone: (760) 431-7922 ext. 134
Email: rburda@aaltoscientific.com

Date Prepared: January16, 2014

**B. Device Identification**

| | |
|---|---|
| Product Trade Name: | Audit® MicroControls™ Linearity FD Tumor Markers II |
| Common Name: | Multi-Analyte Controls, All Kinds (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**

K082717 Audit® MicroCV™ Tumor Markers Linearity Set

**D. Intended Use**

The Linearity FD Tumor Markers II is an assayed quality control material intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), Prostate-specific antigen-total (PSA), Carbonic Anhydrase-125 (CA-125), Carbonic Anhydrase 19-9 (CA19-9), Carbonic Anhydrase 27-29 (CA27-29)/(BR), free-PSA (fPSA), and Carbonic Anhydrase 15-3 (CA15-3).

The Linearity FD Tumor Markers II is for In Vitro Diagnostic use only.

**E. Technical Characteristics Compared** to Predicate Device

| **Characteristics** | Audit® MicroControls™ Linearity FD Tumor Markers II (New Device) | Audit® MicroCV™ Tumor Markers Linearity Set (Predicate Device, K082717) |
|---|---|---|
| **Intended Use** | The Linearity FD Tumor Markers II is an assayed quality control material intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), Prostate-specific antigen-total (PSA), Carbonic Anhydrase-125 (CA-125), Carbonic Anhydrase 19-9 (CA19-9), Carbonic Anhydrase 27-29 (CA27-29)/(BR), free-PSA (fPSA), and Carbonic Anhydrase 15-3 (CA15-3).<br><br>The Linearity FD Tumor Markers II is for In Vitro Diagnostic use only. | The Audit™ MicroCV™ Tumor Markers Linearity Set consists of five levels in Human based serum. Each level contains the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), CA-125, CA15-3, Prostate specific antigen-free (free PSA), total PSA. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments. This product may be used for proficiency testing in interlaboratory surveys. |
| **Number of Levels per Set** | 5 | 5 |
| **Contents** | 5x1ml (two sets) | 5x1ml (one set) |
| **Matrix** | Human Based Serum and bovine based serum | Human Based Serum |
| **Type of** | Clinical Chemistry | Clinical Chemistry |

| **Analytes** | | |
|---|---|---|
| **Form** | Freeze Dried | Freeze Dried |
| **Storage** | 2-8ºC | 2-8ºC |
| **Reconstituted Stability** | fPSA-7 days at 2-8ºC, Remaining analytes-14 days at 2-8ºC | 7 days at 2-8ºC |
| **Sterile** | No | No |
| **Analytes** | AFP, CEA, CA-125, CA15-3, fPSA, total PSA, CA19-9, CA27-9 | AFP, CEA, CA-125, CA15-3, fPSA, total PSA |
| **Number of Analytes per Vial** | 6 (Set 1) and 2 (Set 2) | 6 |

## F. Device Description

The Audit® MicroControls™ Linearity FD Tumor Markers II product is an in-vitro diagnostic device consisting of two sets of five levels of liquid, linearity/QC material. Set 1 contains the analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), Prostate-specific antigen-total (PSA), Carbonic Anhydrase-125 (CA-125), Carbonic Anhydrase 19-9 (CA19-9), and Carbonic Anhydrase 27-29 (CA27-29) (BR) and additives in human serum. Set 2 contains the analytes: free-PSA (fPSA), and Carbonic Anhydrase 15-3 (CA15-3) and additives in human serum and bovine serum. For each set there are five levels labeled A, B, C, D and E. Both sets contain 1ml for each level. 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

Analyte value assignment for Level A through Level E was performed on Siemens Advia Centaur for the analytes: AFP, CEA, PSA, CA125, CA27-29 (BR), and CA15-3 using the corresponding reagent. Analyte value assignment for the analytes: CA19-9, and free-PSA were performed on Abbott Architect i1000SR using the corresponding reagent. Each analyte was measured multiple times. The mean value of each analyte was used to establish target concentration value at each level. All supporting data is retained on file at Aalto Scientific, Ltd.

<u>AMR</u>
AFP: 1.3-1000 ng/ml
CEA: 0.5-100ng/ml
PSA: 0.01-1000 ng/ml
CA125: 2-600 U
CA27-29 (BR): 3.5-450 U/ml
CA15-3: 0.5-200 U/ml
CA19-9: 1.2-1200 U/ml
fPSA: 0.008-30 ng/ml

## H. Summary of Performance Data

Stability studies have been performed to determine the reconstituted 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
Vials from two lots of finished product are stored at 2-8ºC (real time vials) and -80ºC (Day0 vials). Samples are taken at two different time points. The analyte values from the real time vials are compared to the Day0 vials (both tested in duplicate). The product is determined to meet its predicted shelf life if the % difference of the real time mean values compared to the Day0 mean value is within the acceptance criteria. All supporting data is retained on file at Aalto Scientific, Ltd.

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

Reconstituted Vial-Accelerated Stability+Real Time Stability
Real time stability studies were conducted at the end of accelerated stability studies to establish the reconstituted 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:

*Reconstituted Stability*: Once a vial has been opened and reconstituted, the product will be stable for 14 days when stored tightly capped at 2-8º C.

## I. Expected Values

Value assignment of Audit® MicroControls™ Linearity FD Tumor Markers II have been performed to determine the expected values of the AFP, CEA, CA-125, CA15-3, fPSA, total PSA, CA19-9, CA27-9 analytes. Each analyte value assignment for Level A through Level E was performed on Siemens Advia Centaur using the corresponding reagents for AFP, CEA, PSA, CA125, CA27-29 (BR), and CA15-3. Each analyte value assignment for Level A through Level E was performed on Abbott Architect i1000SR using the corresponding reagent for CA19-9, and free-PSA. Each analyte was measured multiple times and the mean value of each analyte was used to establish target values at each level. The target ranges were calculated as +/-20% of the target mean values.

All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

| AFP (ng/ml)/Siemens Advia Centaur | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 8.2 | 6.5-9.8 | 264.5 | 211.6-317.4 | 515.4 | 412.3-618.5 | 785.1 | 628.1-942.1 | 1030.7 | 824.5-1236.8 |

| CEA (ng/ml)/Siemens Advia Centaur | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 3.01 | 2.41-3.62 | 29.36 | 23.49-35.24 | 54.99 | 43.99-65.99 | 76.86 | 61.49-92.23 | 106.89 | 85.51-128.27 |

| PSA (ng/ml)/Siemens Advia Centaur | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 0.22 | 0.18-0.27 | 27.71 | 22.17-33.25 | 57.12 | 45.70-68.55 | 85.87 | 68.69-103.04 | 115.07 | 92.05-138.08 |

| CA125 (U/ml)/Siemens Advia Centaur | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 11.0 | 8.8-13.2 | 162.4 | 129.9-194.8 | 302.3 | 241.8-362.7 | 464.9 | 371.9-557.9 | 620.1 | 496.1-744.1 |

| CA27-29 (U/ml)/Siemens Advia Centaur | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 11.61 | 9.29-13.93 | 114.97 | 91.98-137.96 | 222.32 | 177.85-266.78 | 320.85 | 256.68-385.02 | 429.50 | 343.60-515.40 |

| CA15-3 (U/ml)/Siemens Advia Centaur | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 1.3 | 1.1-1.6 | 50.6 | 40.5-60.8 | 100.9 | 80.7-121.1 | 145.5 | 116.4-174.6 | 200.1 | 160.0-240.1 |

| CA19-9 (U/ml)/Abbott Architect i1000SR | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 7.01 | 5.60-8.41 | 295.48 | 236.38-354.57 | 594.98 | 475.98-713.98 | 878.37 | 702.70-1054.04 | 1143.61 | 914.89-1372.34 |

| free-PSA (ng/ml)/Abbott Architect i1000SR | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 |
| 0.016 | 0.013-0.019 | 7.533 | 6.026-9.039 | 16.083 | 12.866-19.299 | 25.475 | 20.380-30.570 | 32.219 | 25.775-38.663 |

## 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.