K112143

JAN 3 1 2012

Aalto Scientific, Ltd.

510(k) Notification
Audit® MicroCV™ T-Uptake Calibration/Verification Set

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
Telephone: (760) 431-7922
Fax: (760) 431-6824

B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
Telephone: (760) 431-7922 Ext. 118
E-mail: dlyakov@aaltoscientific.com

C. Date of Summary Preparation

January 30, 2012

D. Device Identification

Product Trade Name:	Audit® MicroCV™ T-Uptake Calibration/Verification Set
Common Name:	T-Uptake Calibration/Verification
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJX

Device to Which Substantial Equivalence is Claimed:

Product Trade Name:	Audit® MicroCV™ Immunoassay Linearity Set Aalto Scientific, Ltd., Carlsbad, CA K062668

E. Description of the Device

The Audit® MicroCV™ T-Uptake Calibration/Verification is a human and bovine albumin based, liquid set of QC material. Each level of the set contains T-Uptake analyte. It is used to confirm the proper calibration, linear operating range, and reportable range of T-Uptake. Level A is near the lower limit level and Level E has concentrations near the upper limit of P-Modular analyzer. Levels B, C, and D are prepared in a manner such that an equal distance exists between each consecutive level.

F. Statement of Intended Use

Audit® Micro*CV*™ T-Uptake Calibration/Verification Set consists of five levels of human and bovine albumin based serum containing T-Uptake. The Audit® MicroCV™ T-Uptake Calibration/Verification Set is a quality control material intended for use in the quantitative verification of calibration and reportable range of the Roche T-uptake Assay when performed on the P-Modular Analyzer 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™ T-Uptake Calibration/Verification is for In Vitro Diagnostic use only.

A. Summary of Performance Data

Stability studies have been performed to determine the shelf life for the Audit® MicroCV™ T-Uptake Calibration/Verification Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Open Bottle: 10 days, when stored at 2 - 8° C.

Shelf Life: Two Years, when stored unopened at 2 - 8° C.

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

B. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroCV™ T-Uptake Calibration/Verification Set (K112143)	Audit™ MicroCV™ Immunoassay Linearity Set (K062668)
Intended Use	Audit® MicroCV™ T-Uptake Calibration/Verification Set consists of five levels of human and bovine albumin based serum containing T-Uptake. The Audit® MicroCV™ T-Uptake Calibration/Verification Set is a quality control material intended for use in the quantitative verification of calibration and reportable range of the Roche T-uptake Assay when performed on the P-Modular Analyzer 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™ T-Uptake Calibration/Verification is for In Vitro Diagnostic use only.	The Audit® MicroCV™ Immunoassay Linearity consist of five levels of human and bovine serum albumin matrix. Each level contains the following analytes: Cortisol, Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, Total T3, Total T4,TSH, and Vitamin B12. These 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 and to perform CLIA directed calibration verification for these same analytes in accordance with current CLIA-88 guidelines and regulations. In addition, level A-E of this product may be used as unassayed quality control material for these analytes or as an assayed quality control material for the analyzer systems specified in the package insert. It is not intended to be used as an assayed quality control material for any other analyzer system.
Number of Analytes per via	1	17
Number of levels per set	5	5
Contents	5 x 1 mL	5 x 5 mL
Matrix	Human and Bovine Albumin	Human and Bovine Albumin
Type of Analytes	T-Uptake	Cortisol, Digoxin, Estradiol, Ferritin, Folate, Free T4, FSH, hCG, LH, Progesterone, Prolactin, Testosterone, Total PSA, Total T3, Total T4,TSH, and Vitamin B12
Form	Liquid	Lyophilized
Storage	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Open Vial Stability	10 days at 2 to 8° C	5 days at 2 to 8°

C. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Aalto Scientific, Ltd.
c/o Dessi Lyakov
Regulatory Affairs Manager
1959 Kellogg Ave.
Carlsbad, CA 92008

JAN 31 2012

Re: k112143
Trade/Device Name: Audit® MicroCV™ T-Uptake Calibration/Verification Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: January 17, 2012
Received: January 18, 2012

Dear Ms. Lyakov:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Aalto Scientific, Ltd.

510(k) Notification
Audit® MicroCV™ T-Uptake Calibration/Verification Set

Indications for Use

510(k) Number: K112143

Device Name: Audit® MicroCV™ T-Uptake Calibration/Verification Set

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro
Diagnostic Device Evaluation and Safety

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