Aalto Scientific, Ltd.

K100718

SEP 3 2010

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
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B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
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(760) 431-7922, Ext. 118

C. Date of Summary Preparation

February 26, 2010

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ Ammonia/Ethanol Linearity Set
Common Name:	Ammonia/Ethanol Linearity
Classification Name:	Multi-analyte controls (Assayed and Unassayed)
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

E. Device to Which Substantial Equivalence is Claimed

Product Trade Name:	Document Ammonia/Ethanol CAL•VER® Microgenics Corporation, Fremont, Ca K944338

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F. Description of the Device

The Audit™ MicroCV™ Ammonia/Ethanol Linearity Set is a protein (bovine) based calibration verification material containing multiple levels used to confirm proper calibration, linear operating range, and reportable range of the measured analyte. Level A has concentration near the lower limit level and Level E has concentrations near the upper limit level of instruments. Levels B – D are related by linear dilution of Level A and Level E.

G. Statement of Intended Use

The Audit MicroCV Ammonia/Ethanol Linearity Set is assayed quality control material consisting of five levels protein (bovine) based serum. Each level contains Ammonia and Ethanol analytes. The five levels demonstrate a linear relationship to each other for Ammonia and Ethanol analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Ammonia and Ethanol. This product may be used as unassayed quality control material for Ammonia and Ethanol analytes. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit MicroCV Ammonia/Ethanol Linearity Set is "For In Vitro Diagnostic Use Only".

I. Summary of Performance Data

Stability studies have been performed to determine stability and shelf life for the Audit™ MicroCV™ Ammonia/Ethanol Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Open Vial Stability: Once a vial has been opened, all analytes will be stable for 2 days when stored stoppered at 2 - 8° C.

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

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

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H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit™ MicroCV™ Ammonia/Ethanol Linearity Set (K100718)	Microgenics Document Ammonia/Ethanol CAL VER (K944338)
Intended Use	The Audit MicroCV Ammonia/Ethanol Linearity Set is assayed quality control material consisting of five levels protein (bovine) based serum. Each level contains Ammonia and Ethanol analytes. The five levels demonstrate a linear relationship to each other for Ammonia and Ethanol analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Ammonia and Ethanol. This product may be used as unassayed quality control material for Ammonia and Ethanol analytes. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit MicroCV Ammonia/Ethanol Linearity Set is "For In Vitro Diagnostic Use Only."	DOCUMENT Ammonia/Ethanol CAL•VER® solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification, verification of the Analytical Measurement Range (AMR), and verification of reportable ranges of manual, automated and semi-automated analytical chemistry systems.
Number of Analytes per vial	2	2
Number of levels per set	5	5
Contents	5 x 2 mL	10 x 3 mL
Matrix	Protein-based, liquid	Protien-based, liquid
Type of Analytes	Ammonia Ethanol	Ammonia Ethanol
Form	Liquid	Liquid
Storage	2 to 8° C Until expiration date	-20° C Until expiration date
Open Bottle Stability	2 days at 2 to 8° C	2 to 8° C Until expiration date

J. 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

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Aalto Scientific, Ltd.
c/o Dessi Lyakov
1959 Kellogg Avenue
Carlsbad, CA 92008

Re: k100718
Trade Name: Audit MicroCV Ammonia/Ethanol Linearity Set, Model K712M-5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJY
Dated: August 20, 2010
Received: August 20, 2010

SEP 3 2010

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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/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 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 C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

NewSEltr.

Aalto Scientific, Ltd.

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Indications for Use

510(k) Number: K100718

Device Name: Audit™ MicroCV™ Ammonia/Ethanol Linearity Set

Indications For Use:

"The Audit MicroCV Ammonia/Ethanol Linearity Set is assayed quality control material consisting of five levels protein (bovine) based serum. Each level contains Ammonia and Ethanol analytes. The five levels demonstrate a linear relationship to each other for Ammonia and Ethanol analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Ammonia and Ethanol. This product may be used as unassayed quality control material for Ammonia and Ethanol analytes. The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit MicroCV Ammonia/Ethanol Linearity Set is "For In Vitro Diagnostic Use Only."

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Devices
Evaluation and Safety

510(k) K100718