Aalto Scientific, Ltd.

K101434

510(k) Summary

FDA CDRH DMC
JUL 22 2010
Received

A. Submitter

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

B. Contact Person

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

C. Date of Summary Preparation

May 18, 2010

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ Procalcitonin Linearity Set
Common Name:	Procalcitonin Linearity
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	83
Product Code:	MJX

E. Device to Which Substantial Equivalence is Claimed

Audit™ MicroCV™ General Chemistry Linearity Set
Aalto Scientific, Ltd., Carlsbad, CA
K042318

F. Description of the Device

The Audit™ MicroCV™ Procalcitonin Linearity Set is a bovine serum albumin, freeze dried, five level set of QC material, with each level containing one analyte: Procalcitonin. It is used to confirm the proper calibration, linear operating range, and reportable range of Procalcitonin. 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™ Procalcitonin Linearity Set is assayed quality control material consisting of five levels of Procalcitonin analyte in bovine serum albumin. The five levels demonstrate a linear relationship to each other for the Procalcitonin analyte. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for Procalcitonin. This product may be used as an assayed quality control material for Procalcitonin analyte.

I. Summary of Performance Data

Stability studies have been performed to determine the shelf life for the Audit™ MicroCV™ Procalcitonin 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 reconstituted, Procalcitonin analyte will be stable for 5 days when stored tightly capped at 2-8 C.

Shelf Life: One year at 2 - 8° C.

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

Aalto Scientific, Ltd.

H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit™ MicroCV™ Procalcitonin Linearity Set (New Device)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)
Intended Use	The Audit™ MicroCV™ Procalcitonin Linearity Set is assayed quality control material consisting of five levels of Procalcitonin analyte in bovine serum albumin. The five levels demonstrate a linear relationship to each other for the Procalcitonin analyte. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for Procalcitonin. This product may be used as an assayed quality control material for Procalcitonin analyte.	Audit™ MicroCV™ General Chemistry Linearity Set is assayed quality control material consisting of human based serum. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures. This product may also be used as unassayed quality control material for these same analytes.
Number of Analytes per vial	1	30
Number of levels per set	5	5
Contents	5 x 1 mL	5 x 5 mL
Matrix	Bovine Serum Albumin	Human Based Serum
Type of Analytes	Clinical Chemistry	General Chemistry
Form	Lyophilized	Lyophilized
Stabilizers	None	None
Preservatives	Sodium azide	Sorbitol Sodium azide
Storage	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Open Vial Stability	5 days at 2-8 C	7 days at 2 to 8° C except for enzymes and bilirubin, which are 48 hours

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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUL 2 2 2010

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

Re: k101434
Trade/Device Name: Audit™Micro CV™Procalcitonin Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I
Product Code: MJX
Dated: May 21, 2010
Received: May 24, 2010

Dear Mr. 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 class II (Special Controls), it may be subject to such 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. This letter will allow you to begin marketing your device as described in your Section

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. 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 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~unknown~~ K 101434

Device Name: Audit™ MicroCV™ Procalcitonin Linearity Set

Indications For Use:

The Audit™ MicroCV™ Procalcitonin Linearity Set is assayed quality control material consisting of five levels of Procalcitonin analyte in bovine serum albumin. The five levels demonstrate a linear relationship to each other for the Procalcitonin analyte. It is intended to simulate human patient serum samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for Procalcitonin. This product may be used as an assayed quality control material for Procalcitonin analyte.

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

510(k) K101434