FEB 15 2011

Axis-Shield PoC AS
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Special 510(k) Summary

This summary of 510(k) safety and efficacy information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K110056

Submission type:	**510 (k) Special;** modification of a previously cleared device
Submitter/Owner:	Axis-Shield PoC AS P.O. Box 6863 Rodelokka, N-0504 Oslo, Norway
Contact person:	Ms. Kari Skinnemoen, Regulatory Affairs Manager E-mail: kaskin@axis-shield.com
Preparation date:	6 January 2011

Proprietary and Established Names of Previously Cleared Device:

Afinion™ AS 100 Analyzer
Afinion™ HbA1c
Afinion™ HbA1c Controls

Regulatory Information of Previously Cleared Device

510(k) no.: k050574
Device Classification: Class I, II
Product Codes: JQT, LCP, JJX
CLIA complexity: Waived

Regulatory Information of Other Cleared Device applicable to this Submission

510(k) no.: k072409
Trade/Device Name: Afinion™ ACR and Afinion™ ACR Control
Device Classification: Class II
Product Codes: JFY, JIR, JJY

Intended use/Indications for Use of Previously Cleared Device (k050574)

Afinion™ AS100 Analyzer System, consisting of Afinion™ AS100 Analyzer, Afinion™ Test Cartridges and Afinion™ Controls is for in-vitro diagnostic use only. Afinion™ AS100 Analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges.

Afinion™ HbA1c is an in-vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, % HbA1c) in human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with

diabetes mellitus.
Afinion™ HbA1c Controls have been designed for use with the Afinion™ AS100 Analyzer System. Quality control using the Afinion™ HbA1c Control should be done to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable result

Description of Device Modification:
The Afinion™ AS100 Analyzer is equipped with a new component/accessory: Afinion™ Data Connectivity Converter (ADCC). The ADCC is only for use together with the Afinion™ AS100 Analyzer.

The ADCC is a small device for automatic transfer of data, including patient and control assay results, from the Afinion™ Analyzer to a laboratory information system (LIS) or another electronic journal system. It converts the format of the results from the proprietary Afinion™ Analyzer protocol to a standardized protocol (HL7 or ASTM). The main functionality for software contained in the Afinion™ Data Connectivity Converter is to:

- Extract test result data from the Afinion™AS100 Analyzer
- Convert the transmission format to a configurable standard protocol and forward the result data on Ethernet
- Provide user feedback on LEDs
- Provide user interface for configuration and software upgrade through a web interface
- Provide functionality to reset device to default/factory software status.

Comparison Information:
Afinion™ AS100 Analyzer equipped with Afinion™ Data Connectivity Converter (ADCC) is substantial equivalent to the predicate device: Afinion™ AS100 Analyzer. There is no change in indication/intended use, fundamental scientific technology, analytical performance or safety of the Afinion™ AS100 Analyzer System, consisting of Afinion™ AS100 Analyzer, Afinion™ Test Cartridges and Afinion™ Controls.

Design Control Activities
Level of concern: moderate. The software device is an accessory/component to a medical device that has a moderate level of concern (Afinion™ AS100 Analyzer).

Hazards analysis has been performed during development regarding installation and operation of Afinion™ Data Connectivity Converter together with the Afinion AS100 Analyzer addressing risks for patient, operator and environment. No hazards have been assessed to have unacceptable risk.

The design development and the verification/validation have been performed according to the Design Plan. Software code reviews, software module testing and functional testing have been performed. Based on the results the Afinion™ Data Connectivity Converter is considered to be in agreement with design input/design specifications.

Safety standards for electrical equipment for laboratory and IVD use
Afinion™ AS100 Analyzer equipped with Afinion™ Data Connectivity Converter has been tested and found to be in conformity with IEC, UL, CAN/CSA-C22.2: 61010-1 "Safety requirements for electrical equipment for measurement, control, and laboratory use", IEC 61010-2-081 "Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes" and IEC 61010-2-101 "Particular requirements for *in vitro* diagnostic (IVD) medical equipment".

Electromagnetic compatibility (EMC) standards
Afinion™ AS100 Analyzer equipped with Afinion™ Data Connectivity Converter has been tested and found to be in conformity with EN 61326-1:2006 "Electrical equipment for measurement, control, and laboratory use – EMC requirements", EN 61326-2-6:2006 "*In vitro* diagnostic (IVD) medical equipment" and CFR 47: Telecommunications, Chapter I- FCC Part 15 – Radio Frequency Devices – Subpart B: unintentional radiators (2009).

Labeling
The labeling is updated by providing instructions for installation and use of the Afinion™ Data Connectivity Converter in a separate User Manual, and by placing the ETL mark on the label, stating compliance with relevant safety standards for electrical equipment for laboratory use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 15 2011

Axis Shield PoC AS
c/o Ms. Kari Skinnemoen
Regulatory Affairs Manager
PO Box 6863 Rodelokka,
Oslo, N-0504, Norway

Re: k110056
Trade Name: Afinion™ AS100 Analyzer
Regulation Number: 21 CFR §864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Codes: LCP, JQT, JJX, JIR, JFY, JJY, and DCK
Dated: January 6, 2011
Received: January 10, 2011

Dear Ms. Skinnemoen:

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 Parts 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,

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

Enclosure

Indications for Use Form

510(k) Number (if known): k110056
Device Name: Afinion™ AS100 Analyzer

Indications for Use:
Afinion™ AS100 Analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges. The Afinion™ Data Connectivity Converter (ADCC) is a small device for automatic transfer of data, including patient and control assay results, from the Afinion™ Analyzer to a laboratory information system or another electronic journal system.

Afinion™ AS100 Analyzer System, consisting of Afinion™ AS100 Analyzer with Afinion™ Data Connectivity Converter (ADCC), Afinion™ Test Cartridges and Afinion™ Controls is for *in vitro* diagnostic use only.

Afinion™ HbA1c is an in-vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, % HbA1c) in human whole blood. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus.

Afinion™ HbA1c Controls have been designed for use with the Afinion™ AS100 Analyzer System. Quality control using the Afinion™ HbA1c Control should be done to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable result.

The Afinion™ ACR assay is an *in vitro* diagnostic test for quantitative determination of albumin, creatinine and albumin/creatinine ratio (ACR) in human urine using the Afinion™ AS100 Analyzer. The measurement of urine albumin, creatinine and albumin/creatinine ratio, aids in the early diagnosis of nephropathy.

The Afinion™ ACR Control kit contains liquid preparations of albumin and creatinine in citrate buffer. The controls should be used to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable results.

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 OF 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) k110056