

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
INSTRUMENT ONLY TEMPLATE**

**A. 510(k) Number:**

k110056

**B. Purpose for Submission:**

Adding the Afinion™ Data Connectivity Converter (ADCC) to a previously cleared device (k050574)

**C. Manufacturer and Instrument Name:**

Axis- Shield PoC AS, Afinion AS100 Analyzer

**D. Type of Test or Tests Performed:**

The Afinion AS 100 Analyzer system is cleared for the Afinion HbA1c Assay (k050574), and the Afinion ACR test for albumin and creatinine in urine (k072409).

**E. System Descriptions:**

1. Device Description:

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.

## 2. Principles of Operation:

The Afinion™ test system is a closed system consisting of the Afinion™ AS100 Analyzer and the Afinion™ Test Cartridges. The AS100 is a multi-assay analyzer for point-of-care use.

The analyzer utilizes a digital camera and Light Emitting Diodes (LEDs) to perform two kinds of measurements; reflection measurement (amount of light reflected from a membrane) and transmission measurement (amount of light propagating through a liquid). The analyzer comes to the user already calibrated, and the calibration information is placed on the cartridge bar code.

The analyzer performs optical, electronic and mechanical checks on the capillary tube, the test cartridge, and individual processing steps. If the analyzer detects an error the assay will be interrupted and patient results are not reported. An error message will be displayed. The operator refers to the User Manual for interpretation of the error message.

To perform a test the capillary-like collection device is used to draw up either a patient or control sample. The collection device is inserted into the test cartridge then placed in the cartridge chamber of the analyzer. The lid is closed and the cartridge is transported into the analysis compartment. Test and lot specific information read from the barcode label tells the analyzer how to process the cartridge. The sample and reagents are automatically transferred between the wells of the cartridge. A monochrome solid-state camera monitors the entire process. When the assay is completed, LEDs illuminate the final reaction area, which can be either a colored membrane or a reaction well. The camera detects the reflected or transmitted light, which is converted to a test result and displayed on the screen. When the user accepts the result, the lid opens and the used cartridge is removed and discarded.

The Afinion™ Data Connectivity Converter (ADCC) is a small device to be used together with Afinion™ AS100 Analyzer (Analyzer), and will be used for automatic transfer of patient and control assay results from Analyzer to a laboratory information system (LIS) or another electronic journal system. It converts the format of the results from the proprietary Analyzer protocol to a standardized protocols used by the LIS or other electronic journal system.

The software in the ADCC is implemented in a modularized way and the operation of the software is based on interrupts, generated by timers or external events, driving the actions of the software.

3. Modes of Operation:

See k050574

4. Specimen Identification:

See k050574

5. Specimen Sampling and Handling:

See k050574

6. Calibration:

See k050574

7. Quality Control:

See k050574

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes \_\_\_X\_\_\_ or No \_\_\_\_\_

**F. Regulatory Information:**

1. Regulation section:

21 CFR 864.7470 – Glycosylated Hemoglobin Assay

21 CFR 862.2400 – Densitometer/Scanner (Integrating, Reflectance, TLC, or Radiochromatogram) for Clinical Use

21 CFR 862.1660 – Quality Control Material (Assayed and Unassayed)

21 CFR 862.1645 – Urinary Protein or Albumin (Nonquantitative) Test System

21 CFR 862.1225 – Creatinine Test System

21 CFR 862.1660 – Quality Control Material (Assayed and Unassayed)

21 CFR 866.5270 – C-Reactive Protein Immunological Test System

2. Classification:

Class II, I, I, I, II, I and II, respectively

3. Product code:

LCP, JQT, JJX, JIR, JFY, JJY, and DCK respectively

4. Panel:

81 (Hematology and Pathology), and 75 (Chemistry) respectively

**G. Intended Use:**

1. Indication(s) for Use:

Afinion™ AS100 Analyzer with Afinion™ Data Connectivity Converter (ADCC) is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges. 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 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.

2. Special Conditions for Use Statement(s):

The device is for in vitro diagnostic prescription use. It is also intended for Point-of-Care (POC) use.

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

k050574: Afinion™ AS 100 Analyzer, Afinion™ HbA1c, Afinion™ HbA1c Controls

2. Comparison with Predicate Device:

<b>Reagent Similarities and Differences</b>		
<b>Item</b>	<b>Candidate Device: Afinion AS 100 Analyzer with Afinion Data Connectivity Converter (k110056)</b>	<b>Predicate Device: Afinion AS 100 Analyzer (k050574)</b>
Intended Use	Afinion™ AS100 Analyzer is a compact multi-assay analyzer for point-of-care testing, designed to analyze the Afinion™ Test Cartridges.	Same
Measurement	Reflection measurement and transmission measurement	Same
Calibration	Comes calibrated, information on the cartridge bar code	Same
Accessory	Afinion Data Connectivity Converter for automatic transfer of data, including patient and control assay results	None
Data Transfer	Automatic to laboratory information system ( LIS) or other electronic journal systems	Manual
Data Format	HL7 or ASTM	Displayed on the analyzer screen

**I. Special Control/Guidance Document Referenced (if applicable):**

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff

Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)

In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions

Guidance for Industry and FDA Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s)

Guidance for Off-the-Shelf Software Use in Medical Devices; Final

Frequently Asked Questions on the New 510(k) Paradigm; Final

**J. Performance Characteristics:**

1. Analytical Performance:

*a. Accuracy:*

The device performance is the same as the predicate device, therefore new accuracy studies were not performed.

*b. Precision/Reproducibility:*

The device performance is the same as the predicate device, therefore new precision studies were not performed.

*c. Linearity:*

The device performance is the same as the predicate device, therefore new linearity studies were not performed.

*d. Carryover:*

The device performance is the same as the predicate device, therefore new carryover studies were not performed.

*e. Interfering Substances:*

The device performance is the same as the predicate device, therefore new interference studies were not performed.

2. Other Supportive Instrument Performance Data Not Covered Above:

The Sponsor conducted testing to verify HL7 and ASTM communications protocols were implemented as intended. They provided the Afinion™ Data Connectivity Converter Interface HL7 Data Sheet, which describes the Data Connectivity Protocol (patient and control records) for LIMS connectivity based on the HL7 (health level 7) protocol in the ADCC for the Afinion™ AS100

Analyzer. It describes the protocol and the format of the records returned from the Analyzer, gives examples, and highlights issues to be especially addressed; all needed by the programmer that shall interface to this protocol on the LIMS side.

The Afinion™ Data Connectivity Converter Interface ASTM Data Sheet describes the Data Connectivity Protocol (patient and control records) for LIMS connectivity based on the ASTM 1381 – 95 ("Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems") - protocol in the ADCC for the Afinion™ AS100 Analyzer. It describes the protocol and the format of the records returned from the Analyzer. It also gives examples and highlights issues to be especially addressed; all needed by the programmer that shall interface to this protocol on the LIMS side.

The Sponsor provided System Level functional requirements testing in the "Summary report: Verification of Afinion™ Data Connectivity Converter" which contains testing information of the entire system, plus verifying the accessory is packaged with necessary cabling and a User Manual with information on where to find the communication protocols ASTM and HL7

**K. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**L. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.