Section 6 - 510(k) Summary of Safety and Effectiveness

K071466

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

OCT - 9 2007

Submitter information

Contact person: Noor Malki
Manager, Regulatory Affairs & Compliance

Address: Siemens Medical Solutions Diagnostics
Point of Care (POC) Products
2 Edgewater Drive
Norwood, MA 02062

Phone: 781-269-3401

Date summary prepared: May 25, 2006

Device Information

Proprietary Name: DCA Vantage™

Common Name: Test system for hemoglobin A1c, albumin and creatinine.

Classification Name:

- Glycosylated Hemoglobin Assay
- Urinary protein or albumin test system
- Creatinine test system

Predicate Device

Element	Predicate (unmodified device)
Device Name	DCA 2000+ Analyzer
Classification Name and Title 21 CFR	Glycosylated Homoglobin Assay ✓(864.7470) II Urinary Protein or Albumin Test System ✓(862.1645) II Creatinine Test System (862.1225)
510(k) Numbers	• DCA 2000 System for Hemoglobin A1c **(K951361)** - LCP • DCA 2000+ Microalbumin / Creatinine Assay **(K963142)** DIR
Manufacturer	Bayer HealthCare LLC (currently Siemens Medical Solutions Diagnostics)
Class	I & II
Panel	Hematology & Pathology Devices Clinical Chemistry & Clinical Toxicology
CLIA Complexity	DCA 2000+ Glycosylated Hemoglobin Assay – **Waived** DCA 2000+ Microalbumin /Creatinine Assay - **Moderate**

Device Description
The DCA Vantage is a device modification to the previously cleared DCA 2000+. It is a semi-automated, benchtop analyzer designed to quantitatively measure the percent Hemoglobin A1c (HbA1c) in blood and low concentrations of albumin in urine (microalbuminuria), creatinine in urine, and the albumin/creatinine ratio in urine.

Identical to the DCA 2000+, all testing takes place at the analyzer. User steps to introduce the sample to the cartridge and the cartridge to the analyzer are unchanged. To perform a test, the user needs to collect test sample in the capillary holder, insert holder into the cartridge, scan cartridge into the barcode track, place cartridge in its compartment, remove the flexible tab and close the door to automatically start the test. Test results are displayed on screen and measurement is completed in 6-7 minutes.

Statement of Intended Use
The DCA Vantage™ is a semi-automated, benchtop system. It is designed to quantitatively measure the percent Hemoglobin A1c in blood and low concentrations of albumin in urine (microalbuminuria), creatinine in urine, and the albumin/creatinine ratio in urine.

Summary of Technological Characteristics
Similar to the DCA2000+, the DCA Vantage is a spectrophotometer that analyzes the intensity of monochromatic light directed through the cartridge optical window and reports the results in clinically meaningful units. No calculations are required by the user. When an operator swipes a calibration card, the barcode reader reads the card and the system automatically sets the calibration.

The DCA Vantage operating principle, technical platform, instrument and reagent analytical method, test steps, as well as intended use remain the same as the DCA 2000+. In addition, the DCA Vantage utilizes the same test cartridges for HbA1c and Microalbumin / Creatinine currently used on the DCA 2000+.

Design modifications introduced in the DCA Vantage are the addition of integrated printer, increased data storage, improved color LCD touch-screen interface with expanded optional features, updated mechanical and electrical components, updated housing, and the addition of USB/Ethernet connection.

Assessment of Performance
An internal study was conducted to demonstrate the performance of the DCA Vantage™ analyzer (modified device) and assess its substantial equivalence against the DCA 2000+ (unmodified device/predicate device).

Over the study duration, a total of fifty (50) whole blood and fifty (50) urine specimens were evaluated for HbA1c , and microalbumin/creatinine, respectively. All specimens were evaluated on both the DCA Vantage and the DCA 2000+. Based on the data

collected it was concluded that the DCA Vantage meets accuracy requirements using Linear Regression for HbA1c , Albumin, Creatinine, and Albumin Creatinine ratio relative to the DCA 2000+ using clinical specimens. In addition, the DCA Vantage meets the precision performance requirements for HbA1c, Albumin, and Creatinine relative to the DCA 2000+ using quality controls.

Utilizing the established Risk Management process, design modifications introduced in the DCA Vantage underwent a FMECA analysis. As a result, hazards identified were addressed in the design verification and validation testing.

In addition information on Software Development Life Cycle including software requirements specifications, risk management report, and overall verification and validation results were included to provide additional assurance of device performance.

Compliance to Standards

The DCA Vantage is designed and fully meets the following international safety standards:

- **EN 60601-1-2:2001** - Electromagnetic emissions and immunity requirements for medical electrical equipment – group 1 Equipment Class B for non-life supporting equipments
- **EN 60601-1: 1990 + A1:1993 + A2:1995+ A13:1996**
- **EN 55011:1998/A1:1999/A2:2002** - Industrial, scientific and medical (ISM) radio frequency equipment — Radio disturbance characteristics - Limits and methods of measurement - Group 1 Class B ISM emissions requirements
- **IEC 60601-1:1988 + A1:1991 + A2:1995** - Medical Electrical Equipment Part 1: General requirements for safety
- **FCC 47 CFR Part 15** Class B emission requirements
- **CAN/CSA C22.2 No. 601.1-M90** (R1997)

Conclusion

In conclusion, results of performance testing, verification and validation activities demonstrate that the design modifications introduced with the DCA Vantage do not impact safety and effectiveness. The DCA Vantage is similar to the DCA 2000+ in both Technological Characteristics and Intended Use. The data presented is a summary of risk management activities, internal performance testing and software development documentation. The information presented in this Special 510(k) provides confirmation that the DCA Vantage™ is substantially equivalent to the currently marketed DCA 2000+.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 9 2007

Siemens Medical Solutions Diagnostics
Point of Care (POC) Products
c/o Noor Malki
Manager, Regulatory Affairs & Compliance
2 Edgewater Drive
Norwood, MA 02062

Re: k071466
Trade/Device Name: DCA Vantage™, Model 5075
Regulation Number: 21 CFR§864.7470
Regulation Name: Glycosylated Homoglobin Assay
Regulatory Class: Class II
Product Code: LCP, JIR, CGX
Dated: September 5, 2007
Received: September 6, 2007

Dear Noor Malki:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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

510(k) Number (if known): K071466

Device Name: DCA Vantage™

Indications For Use:

The DCA Vantage™ is a semi-automated, benchtop system. It is designed to quantitatively measure the percent Hemoglobin A1c in blood and low concentrations of albumin in urine (microalbuminuria), creatinine in urine, and the albumin/creatinine ratio in urine.

The measurement of hemoglobin A1c concentration is recommended for monitoring the long-term glycemic control of persons with diabetes.

Testing for microalbuminuria (low concentration of albumin in urine) is recommended in patients with insulin-dependent diabetes mellitus (IDDM) as well as patients with non-insulin dependent diabetes mellitus (NIDDM). It is intended for use in both screening for, and monitoring treatment of, microalbuminuria.

Measurement of creatinine is used as a calculation basis to adjust the albumin/creatinine ratio result for varying urine concentrations.

The reporting of albumin/creatinine ratio is recommended for the early detection of kidney diseases.

The DCA Vantage system is for use in laboratories such as: physician office laboratories, clinics, and hospitals.

Tests performed using the DCA Vantage™ are intended for in vitro diagnostic use.

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 Device Evaluation (OIVD)

Carol C. Benson
...ion Sign-Off

...fice of In Vitro Diagnostic Device
...aluation and Safety

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