510(k) Summary for INNOVANCE™ Antithrombin

MAY 28 2009

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

The assigned 510(k) number is: K081769

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
A Siemens Company
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information:
Siemens Healthcare Diagnostics Inc.
500 GBD Drive
Newark, Delaware 19702
Attn: Radames Riesgo
Tel: 305.480.7558
Fax: 305.552.5288

Preparation date: May 5, 2009

2. Device Name: INNOVANCE™ Antithrombin

Classification: Class II
Product Code: JBQ
Panel: Hematology

3. Identification of the Legally Marketed Device:

Dade Behring Berichrom™ Antithrombin III (A) – K933125

4. Device Description:

The INNOVANCE™ Antithrombin assay utilizes a chromogenic measuring principle. An excess of factor Xa is added to citrated plasma. In the presence of heparin, a portion of the enzyme is complexed and inactivated by the antithrombin present in the sample. Excess, uninhibited factor Xa then cleaves a specific chromogenic substrate, causing the release of a dye. The rate of the substrate cleavage is determined by the increase in the absorbance value at 405 nm.

antithrombin + heparin ——————> [antithrombin • heparin]

[antithrombin • heparin] + FXa (excess) —> [antithrombin • heparin • FXa] + FXa (residual)

chromogenic FXa substrate —FXa (residual)——> tripeptide + dye

The release of dye is inversely proportional to the inhibiting activity of the antithrombin in the plasma sample, i.e. the smaller the concentration of functionally active antithrombin, the higher the absorbance signal per time unit.

5. Device Intended Use:

INNOVANCE™ Antithrombin is a chromogenic assay for the automated quantitation of functionally active antithrombin in human citrated plasma and can be used as an aid in the diagnosis of antithrombin deficiency.

6. Medical device to which equivalence is claimed and comparison information:

The INNOVANCE™ Antithrombin reagent is substantially equivalent, and has the same intended use and performance to the Dade Behring Berichrom™ Antithrombin III (A) reagent (K933125).

7. Device Performance Characteristics:

The INNOVANCE™ Antithrombin reagent was compared to the Dade Behring Berichrom™ Antithrombin III (A) reagent on the BCS®/BCS® XP System by evaluating plasma samples with antithrombin activity ranging from 4.8 to 131.3% of the norm. Regression analysis of these evaluations yielded the following equation:

Method Comparison Study

Comparative Method	n	Slope	Intercept	Correlation Coefficient
Berichrom™ Antithrombin III (A) on the BCS®/BCS® XP System	284	1.04	0.34	0.944

Precision studies were conducted with the BCS®/BCS® XP System, as described in the CLSI Guideline EP5-A2, using Control Plasma N (control plasma in the normal range) and Control Plasma P (control plasma in the pathological range) as well as a pathological plasma pool (human plasma pool in the decision range).

Sample	Precision (N = 80)		
	Mean [% of the Norm]	Repeatability CV [%]	Within-device/lab CV [%]
Control Plasma N	95.8	2.8	3.7
Control Plasma P	31.4	2.6	4.5
Pathological Plasma Pool	61.7	1.9	3.5

8. Conclusion:

The proposed INNOVANCE™ Antithrombin device is substantially equivalent to the legally marketed device based upon the correlation studies and the information above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 28 2009

Siemens Healthcare Diagnostics Inc.
c/o Mr. Radames Riesgo
Regulatory Affairs and Compliance Manager
500 GBD Drive MS 514
Newark, DE 19702

Re: k081769
Trade/Device Name: INNOVANCE™ Antithrombin
Regulation Number: 21 CFR 864.7060
Regulation Name: Antithrombin III assay
Regulatory Class: Class II
Product Code: JBQ
Dated: March 23, 2009
Received: March 24, 2009

Dear Mr. Riesgo:

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). 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), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. 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 (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology 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): K081769

Device Name:
INNOVANCE™ Antithrombin

Indications for Use:

INNOVANCE™ Antithrombin is a chromogenic assay for the automated quantitation of functionally active antithrombin in human citrated plasma and can be used as an aid in the diagnosis of antithrombin deficiency.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K081769