510(k) Summary of Safety and Effectiveness for the

FEB 18 2011

ADVIA® Chemistry Liquid Specific Protein Calibrators

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.

A. 510(k) Number: K103701

B. Date of Preparation: December 03, 2010

C. Proprietary and Established Names:

ADVIA® Chemistry Liquid Specific Protein Calibrator

D. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Kira Gordon, Sr. Regulatory Affairs Specialist

Office: (914) 524-2996 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA Chemistry Liquid Specific Protein Calibrator

1. Regulation section: 21 CFR § 862.1150 Calibrator.

2. Classification: Class II

3. Product Code: JIX, calibrator, multi-analyte mixture

4. Panel: Clinical Chemistry

F. Predicate Device:

Randox Liquid Protein Calibrators

ADVIA Chemistry Liquid Specific Protein Calibrator is substantially equivalent to the Randox Liquid Protein Calibrator cleared under K031608 and K061056.

G. Device Description:

ADVIA Chemistry Liquid Specific Protein Calibrator is a multi-analyte, liquid buffered based product containing multiple analytes (proteins derived from human source). The kit consists of 6 vials each of 6 calibrator levels which are ready for use (no preparation is required). The constituent concentrations of these Calibrators are

present at levels 2, 3, 4, 5 and 6. Level 1 is a zero level. The volume per vial is 1.0 mL.

Anti-streptolysin-O (ASO), Alpha-1-Antitrypsin (AAT), Prealbumin (PREALB), Rheumatoid Factor (RF), Immunoglobulin A_2, (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Complement C3 (C3), Complement C4 (C4), Haptoglobin (HAPT), Transferrin (TRF), and Alpha-Acid-Glycoprotein (AAG) are value assigned for ADVIA 1650 Chemistry systems.

In addition the calibrator also contains Ferritin and CRP with no specific value assignment on ADVIA Chemistry systems at this time.

H. Intended Use:

The ADVIA Chemistry Liquid Protein Calibrator is for *in vitro* diagnostic use in the calibration of ADVIA® Chemistry systems for the **Alpha-Acid-Glycoprotein (AAG)**, Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O_2 (ASO_2), Complement C3 (C3), Complement C4 (C4), Haptoglobin (HAPT), Immunoglobulin A_2 (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Prealbumin (PREALB), Rheumatoid Factor (RF), Transferrin (TRF) methods

I. Substantial Equivalence Information:

The ADVIA Chemistry Liquid Specific Protein Calibrator and Randox Liquid Protein Calibrator were compared in the following table.

Item	New Device	Predicate Device (k061056 and k031608)
Intended Use	for *in vitro* diagnostic use in the calibration of ADVIA® Chemistry system for the **Alpha-Acid-Glycoprotein (AAG)***, Alpha-1-Antitrypsin (AAT), Anti-streptolysin-O_2 (ASO_2), Complement C3 (C3), Complement C4 (C4), Haptoglobin (HAPT), Immunoglobulin A_2 (IGA_2), Immunoglobulin G_2 (IGG_2), Immunoglobulin M_2 (IGM_2), Prealbumin (PREALB), Rheumatoid Factor (RF), Transferrin (TRF) methods * - *subject of this submission*	k061056: for in vitro diagnostic use in the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, and Transferrin assays on Clinical Chemistry and Immunoassay systems k031608: for the calibration of ASO, Complement C3, Complement C4, CRP, Ferritin, IgA, IgG, IgM, Prealbumin and Transferrin assays (all neat sample assays). These calibrators also contain a-1-Antitrypsin (AAT) and Rheumatoid Factor (RF) for use in the calibration of AAT and RF assays on the Bayer Advia 1650 analyser only. for the calibration of a-1-antitrypsin, a-1-acid glycoprotein, IgA, IgG, IgM and Transferrin assays which require sample pre-dilution
Formulation / analytes present	Anti-streptolysin-O, Alpha-1-Antitrypsin, Prealbumin, Rheumatoid Factor, Immunoglobulin A Immunoglobulin G, Immunoglobulin M,	same

	Complement C3, Complement C4, Haptoglobin, Transferrin, Ferritin, Alpha-acid-glycoprotein, CRP	
Measured Analytes (value assigned)	Anti-streptolysin-O Alpha-1-Antitrypsin Prealbumin, Rheumatoid Factor, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Complement C3, Complement C4, Haptoglobin, Transferrin, Alpha-acid-glycoprotein, Ferritin - not value assigned but present in the formulation, CRP - not value assigned but present in the formulation	ASO AAT Prealbumin RF IgA IgG IgM Complement C3 Complement C4 HAPT Transferrin Alpha-acid-glycoprotein Ferritin CRP
Instrument	ADVIA® Chemistry Systems	Clinical Chemistry and Immunoassay systems, Abbott Spectrum, Abbott Aeroset, Abbott Architect *i*2000, Architect *i*2000sr, Ace analyser, Bayer Advia 1650, Advia 2400, Advia 1200, Dade Dimension RXL, Dimension AR, Hitachi 704, Hitachi 717, Hitachi 911, Hitachi 917, Hitachi 912, Hitachi 747, Kone progress, AU800, AU600, AU400, AU2700, AU5400, Selectra Vitalab, Synchron CX4, Synchron CX5, Synchron CX7, Synchron LX20, ILAB300, ILAB900, ILAB1800, ILAB600, RX Daytona, RX Imola, Cobas Mira, Cobas Mira S, Cobas Mira Plus systems
Traceability for AAG	International Reference Material CRM 470	same
Matrix	Buffered base	same
Analyte source	Derived from human source	same
Number of levels	Six (the lowest level is a zero-level)	same
Fill Volume	1.0 mL each vial	same
Stability	24 months – shelf-life 28 days open vial	same

J. Conclusion:

The multi-analyte, six level ADVIA Chemistry Liquid Specific Protein Calibrator is substantially equivalent to the Randox Liquid Protein Calibrator. They are identical in composition and both used in calibration of multiple analytes on Chemistry systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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c/o Kira Gordon, Ph.D.
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511 Benedict Ave
Tarrytown, NY 10591

FEB 18 2011

Re: k103701
Trade/Device Name: ADVIA® Chemistry Liquid Specific Protein Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: December 17, 2010
Received: December 20, 2010

Dear Dr. Gordon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Part 801); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

maria m chan

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): k103701

Device Name: ADVIA® Chemistry Liquid Specific Protein Calibrators

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k103701