JUL 28 2010

510(k) Summary of Safety and Effectiveness for the

ADVIA® 2120 systems Body Fluids Application

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: K090346

B. Date of Preparation: July 15, 2010

C. Proprietary and Established Names:

ADVIA® 2120 and 2120i Hematology Analyzer, Body Fluids Application

D. Applicant:

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

Ernest Joseph, Senior Regulatory Affairs Specialist

Office: (914) 524-2431 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA® 2120/2120i Body Fluids Application

1. Regulation section: 21 CFR § 864.5220 Automated Differential Cell Counter
2. Classification: Class II
3. Product Code: GKZ
4. Panel: Hematology

F. Predicate Device:

COULTER® LH 750 Body Fluids Application 510(K) # K030606

G. Device Description:

Summary and Explanation: Peritoneal and pleural fluids are serous fluids found in the serous membranes that line the peritoneal and pleural body cavities. Under normal conditions the amount of fluid in the serous membranes is very small. An effusion, the accumulation of fluid within the serous membranes, is a symptom of a pathologic process that may be transudative or exudative in origin.

Peritoneal Dialysis (PD) is a procedure that can be used to treat patients with renal disease. PD works on the principle that the mesothelial cells of the serous membrane lining the peritoneum function as a filter to remove the toxic substances that accumulate in blood. Peritonitis is a serious complication in patients who undergo PD.

Total Nucleated Cell (TNC) and RBC enumeration is a part of the clinical laboratory assessment of pleural, peritoneal, and PD fluids. The ADVIA 2120/2120i Body Fluid application TNC and RBC counts are to be used in conjunction with other diagnostic information and the attending healthcare professional's evaluation of the patient's condition.

Principles of the Procedure: The ADVIA 2120/2120i Body Fluid Application uses the Basophil/Lobularity and RBC/Platelet channels to enumerate the TNC and RBC counts. The TNC count is derived from the Basophil/Lobularity channel. The ADVIA 2120/2120i BASO reagent contains surfactant and phthalic acid which, in the presence of low heat in the Baso channel reaction chamber, lyses RBCs and strips the cytoplasmic membrane from all leukocytes except basophils. This cell suspension is subsequently passed through the flow cell. The cell suspension is intercepted by light from the laser diode where the low-angle light scatter (2° to 3°) and high-angle light scatter (5° to 15°) signals of each cell are counted.

The RBC count is derived from the RBC/Platelet channel. The ADVIA 2120/2120i RBC/Platelet reagent uses sodium dodecyl sulfate and glutaraldehyde to sphere and fix the RBCs. This cell suspension uses the same flow cell and low-angle and high-angle light scatter signals as the Baso channel to count the RBCs. The system automatically reports the TNC and RBC counts in conventional or SI units appropriate for body fluid samples.

H. Intended Use:

The ADVIA 2120/2120i auto-analyzer Body Fluid Application is an in vitro diagnostic test for the enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens collected in K2 or K3 EDTA.

I. Substantial Equivalence Information:

A comparison of the important similarities and differences between the device and the predicate is provided in the following tables:

Similarities		
Characteristics	COULTER® LH 750 Body Fluids Application (Predicate)	Siemens ADVIA 2120/2120i Body Fluids Application
Instrument	Automated Hematology Analyzer	Same as predicate device.
Intended Use	enumeration of the total nucleated cell (TNC) count and RBC count	Same as predicate device.
Dilution	Automated dilution	Same as predicate device
Counts	Automated calculation of counts	Same as predicate device
Differences		
Characteristics	COULTER® LH 750 Body Fluids Application (Predicate)	Siemens ADVIA 2120/2120i Body Fluids Application

Sample Type	Pleural, peritoneal, and Peritoneal Dialysis fluids.	Cerebrospinal fluid, serous fluid, and synovial fluid.
Detection	Impedance technology	Light scatter technology

J. Conclusion:

The ADVIA 2120/2120i Body Fluids Application is substantially equivalent to the COULTER® LH 750 Body Fluids Application (predicate method) for enumeration of RBC and TNC (WBC) in body fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics, Inc
c/o Mr. Ernest Joseph
Senior Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

JUL 2 8 2010

Re: k090346
Trade/Device Name: Body Fluid Application for ADVIA 2120 and the ADVIA 2120i
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 25, 2010
Received: June 28, 2010

Dear Mr. Joseph:

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 class II (Special Controls), 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 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,

Reena Philip

for 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

JUL 2 8 2010

Indications for Use Form

510(k) Number (if known) K090346

Device Name: Body Fluid Application for ADVIA 2120 and the ADVIA 2120i.

Indications for Use:

The ADVIA 2120/2120i auto-analyzer Body Fluid Application is an in vitro diagnostic test for the enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens collected in K2 or K3 EDTA.

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 IF 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) K090346