



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 11, 2017

Siemens Healthcare Diagnostics
Gerard Sadrakula
Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

Re: K162977

Trade/Device Name: ADVIA[®] 2120
ADVIA[®] 2120i

Regulation Number: 21 CFR 864.5220

Regulation Name: Automated Differential Cell Counter

Regulatory Class: Class II

Product Code: GKZ

Dated: August 9, 2017

Received: August 11, 2017

Dear Mr. Sadrakula:

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 Parts 801 and 809); 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,


Leonthena R. Carrington -S

Lea Carrington

Director

Division of Immunology and Hematology Devices

Office of *In Vitro* Diagnostics and Radiological

Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K162977

Device Name
ADVIA 2120/2120i Hematology auto-analyzers

Indications for Use (Describe)

The ADVIA 2120 and ADVIA 2120i with auto slide are quantitative, automated hematology analyzers that provide the following information for in vitro diagnostic use in clinical laboratories:

- A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV.
- A leukocyte differential count consisting of: Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#) Baso (%/#), LUC (%/#).
- A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.
- A nucleated red blood cell count consisting of NRBC (%/#).
- Enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens.

Note: Above measurands are determined (in whole blood, pleural, peritoneal, or peritoneal dialysis specimens) with K2 and/or K3 EDTA anti-coagulants.

- Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), PMN (%/#).

In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



1.10A 510k Summary

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.

510(k) Number: K162977

Date of Preparation: October 19th, 2016. Updated: July 13th 2017

Proprietary and Established Names:

ADVIA®120,
ADVIA®2120,
ADVIA®2120i,

Applicant:

Siemens Healthcare Diagnostics Inc.,
511 Benedict Ave, Tarrytown, NY 10591
Gerard Sadrakula, Regulatory Affairs Specialist
Office: (914) 524-2582
Fax: (914) 524-3579

Regulatory Information:

The ADVIA®2120i is a class 2 analyzer that produces no PMA results.

Predicate Devices:

ADVIA®2120 cleared in k102644
ADVIA®2120i cleared in k102644

Device Description:

The ADVIA 2120i (RoHS/REACH compliant) is a modification of the ADVIA 2120i Hematology System designed to address the following business needs:

- To achieve RoHS & Reach compliance
- To address component obsolescence

Intended Use / Indications for Use:

The ADVIA 2120 and 2120i with autoslide are quantitative, automated hematology analyzers that provide the following information for in vitro diagnostic use in clinical laboratories

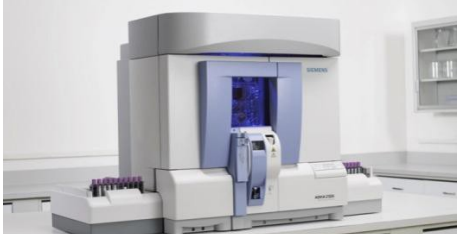
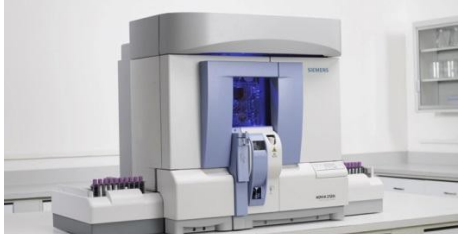
- A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV.
- A leukocyte differential count consisting of: Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#) Baso (%/#), LUC (%/#).
- A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.
- A nucleated red blood cell count consisting of NRBC (%/#).
- Enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens.

Note: Above measurands are determined (in whole blood, pleural, peritoneal, or peritoneal dialysis specimens) with K2 and/or K3 EDTA anti-coagulants.

- Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), PMN (%/#).

In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.

Technology Features Comparison Table:

Technological and Features Comparison Table		
Feature	ADVIA 2120i	ADVIA 2120i (RoHS/REACH Compliant)
		
Type of System	Stand-alone, mid-high volume hematology analyzer	Same
Throughput Rate	120 samples/hour	Same
Intended Use	Quantitative, automated hematology analyzers that provide information for in vitro diagnostic use in clinical laboratories	Same
Sample Type	<i>whole blood, pleural, peritoneal, or peritoneal dialysis specimens with K2 and/or K3 EDTA anti-coagulants</i>	Same
Sample volume	175ul	Same
Reagents	Reagents to support Complete Blood Count, White Blood Cell differential and Reticulocyte analysis	Same
Modes of sampling	3 sampling modes: Manual open tube sampler, manual closed tube sampler and automated closed tube sampler (autosampler).	Same
Data Entry	Keyboard and Touch Screen Monitor	Same
Bar code reading capability	Fixed and Handheld bar code readers	Same
Operating Principals	Flow cytometry, RBC lysing, myeloperoxidase staining of the WBCs and oxazine staining of the reticulocytes, using five channels to analyze blood samples.	Same
Controls	ADVIA 3 in 1 with retics (Normal, Abnormal 1, Abnormal 2) or CBC only (L,N,H) and reticulocytes (L, H)	Same
Calibrator	Commercially available calibrator	Same
Automation Interface Software	Interface software to allow connection to LabCell or Aptio automation	Same
Software	Clinical- V6.2.4	Same
CPU Module	ARM 9 CPU Module	Same

Differences		
Feature	ADVIA 2120i	ADVIA 2120i (RoHS/REACH Compliant)
Signal Processor PCB	Existing non-RoHS compliant Signal Processing PCB. No onboard software	New VHDL implementation of signal processing and monitor/keyboard interface design, to achieve RoHS compliance. No onboard software.
Autosampler Control PCB DAA	Dropped in SMC4 motor controller. Onboard motion control software for 80186 (CPU).	New VHDL implementation of former used discrete components and includes SMC4 motor control. No change to predicate software
Autosampler Control PCB SAA	Dropped in SMC4 motor controller. Onboard motion control software for 80186 (CPU).	New VHDL implementation of former used discrete components and includes SMC4 motor control. No change to predicate software
Reference preAmplifier	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Uses the predicate sensors
PreAmp Power Supply	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Uses the predicate sensors
Laser Diode Driver 1	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Dual Servo Pump	Uses original Software	New VHDL implementation of former used discrete components. Uses original Software
Valve Driver Board	Uses original Software	New VHDL implementation of former used discrete components. Uses original Software
Parallel Node	Uses original Software	New VHDL implementation of former used discrete components. Uses original Software
HGB Interface	Uses original Software	New VHDL implementation of former used discrete components. Uses original Software
Perox Optics Scrambler	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Sensor Amplifier	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Rack Sensor LED	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.

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Indicator Assy DAA	No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Indicator Assy SAA	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Input/Output Q I/O PCBA	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
CAN Scrambler	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Baso Optics Scrambler o Optics Scrambler	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Pneu Valve Scrambler Board Valve Scrambler Board	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
UFC Illumination Board Illumination Board	Provides cosmetic lighting. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
Switch Panel Interface h Panel Interface	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
ID Reader Interface Interface	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.
UFC Valve Scrambler PCB	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.	No onboard software or firmware. Contains some minor RoHS component changes.

Standard/Guidance Document Referenced:

- CLSI EP15-A3: User Verification of Precision and Estimation of bias: Approved Guidelines - Third edition
- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures Approved Guidelines Third edition
- CLSI-EP09-A3: Method comparison and bias estimation using patient samples: Approved Guidelines Third edition
- CLSI-EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures :Approved Guidelines Second edition.
- EN 61010-1:2010 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General Requirements
- EN 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Parts 2- 6: Particular Requirements – In vitro diagnostic (IVD) medical equipment
- ISO 14971:2009 - Medical devices - Application of risk management to medical devices. Including European Deviation in EN ISO 14971:2012.
- IEC 62366:2008 - Medical devices - Application of usability engineering to medical devices

Note: Regarding Standards IEC 62366:2008 no summary report is being supplied. As detailed in section 1.10 Technology Features Comparison Table, “There are no usability changes to the ADVIA 2120i and the ADVIA 2120i(RoHS/REACH compliant system). Therefore the usability file was updated however no separate report has been created. Existing ADVIA 2120i usability has already been approved as part of the prior 510(k102644) submission.

- EN 62304:2006/AC:2008 - Medical device software - Software life-cycle processes
- EN ISO 15223-1:2012 Medical devices - symbols to be used with medical device labels, labeling and information to be supplied

Note: Regarding Standard EN. ISO 15223-1:2012 no summary report is being supplied. As stated in the Operator guide section 2.7, “There are no Major changes to the ADVIA® 120/2120/2120i Operators Guide and the Supplemental Information Research Use Only (RUO) Guide, just some minor formatting and administrative changes to these guides”. Therefore as the original Guides have already been approved as part of the prior 510(k102644) submission.

1.12 Performance Characteristics:

The methods listed below:

- a. Basophil/Lobularity Method
- b. CSF Method
- c. Hemoglobin Method
- d. Peroxidase Method
- e. RBC/Platelet Method
- f. Reticulocyte Method
- g. Body Fluids Method

Had the following studies completed internally via the following sections of this submission:

7.1 Carryover

7.2 Linearity

7.3 Imprecision (within run)

7.4 Accuracy

7.5 Commercial Controls Repeatability and within device Imprecision

7.6 Limit of Quantitation/Detection/Blank

These studies show performance equivalence of the ADVIA®2120i (RoHS/REACH compliant) against the ADVIA®2120 and 2120i. The protocols were tested using CBC, CBC/DIFF, CBC/DIFF/RETIC and Retic only selectivities in each of the sampling modes; opened tube sampling, manual closed tube sampling and automated closed-tube sampling. No non-conformances were observed.

The methods listed below:

- a. Body Fluid
- b. CSF Accuracy

Had the following studies completed at external Clinical sites via sections 8.1 of this submission:

CSF and Body Fluid Accuracy

System Flagging and Method Validation

These studies show performance equivalence of the ADVIA®2120i (RoHS/REACH compliant) against the ADVIA®2120 and 2120i as tested at these External Sites:

- "University of California-San Francisco",
- "Siemens Healthcare Diagnostics"
- "Memorial Sloan-Kettering Cancer Center"

No non-conformances were observed.

There is no change for user needs and intended use in this project.

Our overall conclusion is that:

As a result the ADVIA 2120i Hematology RoHS/REACH analyzer is safe and effective and performs clinically equivalent to the predicate device