July 2, 2021

Siemens Healthcare Diagnostics, Inc.
Julie Warren
Regulatory Affairs Professional
511 Benedict Avenue
Tarrytown, New York 10591

Re: K200256
Trade/Device Name: ADVIA® Chemistry Enzymatic Hemoglobin Ale (Alc_E) Assay
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP, PDJ
Dated: October 12, 2020
Received: October 14, 2020

Dear Julie Warren:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200256

Device Name
ADVIA® Chemistry Enzymatic Hemoglobin Ale (Alc_E) Assay

Indications for Use *(Describe)*
The ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) assay is an in vitro diagnostic assay for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) in human anticoagulated venous whole blood and hemolysate for use on the ADVIA® Chemistry Systems. Measurement of Hemoglobin A1c is used as an aid in the diagnosis and monitoring of long-term blood glucose control in patients with diabetes mellitus, and as an aid in the identification of patients at risk for developing diabetes mellitus.

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.

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510(k) Summary – K200256

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

1. Submitter

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 USA
Establishment Registration Number: 2432235

Submission Contact Person: Julie Warren
Phone: (302) 631-8722
Email: julie.warren@siemens-healthineers.com
Facsimile: (302) 631-6299
Date of Preparation June 17, 2021

2. Device Information

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional. For *in vitro* diagnostic use.

Proprietary Name	ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay	
Common or Usual Name	Hemoglobin A1c Test System	Assay, Glycosylated Hemoglobin
Classification Name	Hemoglobin A1c Test System	Glycosylated hemoglobin assay
Regulation	21 CFR 862.1373	21 CFR 864.7470
Classification	Class II	Class II
Product Code	PDJ	LCP
Review Panel	Clinical Chemistry	Hematology

3. Device Description

The ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) assay measures hemoglobin A1c in human anticoagulated whole blood and hemolysate. The assay consists of three reagents (R1, R2, and Pretreatment Solution), which are liquid and ready to use.

The assay offers both an automated and a manual application. The automated application (A1c_E) lyses the anticoagulated whole blood specimen on the system for the automated application (A1c_E). Samples may also be lysed manually using the ADVIA® Chemistry A1c_E Pretreatment Solution to obtain hemolysate for the manual application (A1c_EM). The two applications yield the same results.

4. Intended Use/Indications for Use

The ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) assay is an *in vitro* diagnostic assay for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) in human anticoagulated venous whole blood and hemolysate for use on the ADVIA® Chemistry Systems. Measurement of Hemoglobin A1c is used as an aid in the diagnosis and monitoring of long-term blood glucose control in patients with diabetes mellitus, and as an aid in the identification of patients at risk for developing diabetes mellitus.

5. Reason for Submission

This Special 510(k) is being filed to seek FDA clearance of a modification to the ADVIA Chemistry Enzymatic Hemoglobin A1c (A1c_E) assay to extend the low end of the analytical measuring range of total hemoglobin (tHb).

A Special 510(k) Premarket Notification is the requested pathway because the following:

- There is no change to the intended use or indications for use.
- There is no change in the fundamental scientific technology.
- There is no change to the principle of operation.
- There is no change to the formulation.
- There is no change to the instrument parameters related to sample volume, reagent volume, mix speed, wavelengths, or read times.

6. Medical Device to Which Equivalence is Claimed

The predicate device for this Special 510(k) submission is the ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) assay cleared under K171771 on December 4, 2017. The classification information is as follows.

Trade Name	Common/Usual Name	Classification	Product Code	Panel
ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay	Hemoglobin A1c Test System; Assay, Glycosylated Hemoglobin	Class II	PDJ; LCP	Clinical Chemistry; Hematology

7. Comparison of Technological Characteristics with the Predicate Device

The similarities and differences to the predicate device were compared side by side in the following table.

Attribute	**Predicate Device** **ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay, K171771**	**Modified Device** **ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay**
Intended Use/ Indications for Use	The ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) assay is an *in vitro* diagnostic assay for the quantitative determination of mmol/mol HbA1c (IFCC) and % HbA1c (DCCT/NGSP) in human anticoagulated whole blood and hemolysate for use on the ADVIA® Chemistry systems. Measurement of Hemoglobin A1c is used as an aid in the diagnosis and monitoring of patients with diabetes mellitus, and as an aid in the identification of patients at risk for developing diabetes mellitus.	Same

Attribute	Predicate Device ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay, K171771	Modified Device ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay
Technology; Type of Test	Quantitative, enzymatic	Same
Measuring Range	3.8 to 14.0% HbA1c (DCCT/NGSP) 18.03 -129.50 mmol/mol HbA1c (IFCC)	Same
Analytical Measuring Range for total hemoglobin	88.98-320.15 µmol/L	74.74-320.15 µmol/L
Specimen Types	Whole blood and Hemolysate	Same
Anticoagulant Types	Dipotassium EDTA Lithium Heparin Sodium Fluoride/Disodium EDTA Tripotassium EDTA	Same
Standardization and Certification	Assay standardization is traceable to International Federation of Clinical Chemistry (IFCC) reference calibrators. Assay is certified with the National Glycohemoglobin Standardization Program (NGSP). The NGSP certification must be renewed annually.	Same
Instrument Platform	ADVIA® 1800 Clinical Chemistry System	Same
Reporting Units	% HbA1c NGSP/DCCT and mmol/mol IFCC	Same

8. Summary of Design Control Activities

A risk analysis and verification activities were conducted as part of design control activities.

8.1 Risk Analysis

A risk analysis was conducted in accordance with ISO 14971:2012 standard, *Medical Devices – Application of Risk Management to Medical Devices* to identify and assess the risks associated with the device modification described in this submission and the risks associated with compliance to the FDA Special Controls set forth in 21 CFR 862.1373(b).

The normal condition and fault condition/failure mode were identified for each risk. Risk mitigations were identified, and effectiveness confirmed through verification activities.

8.2 Verification Activities

Based on the risk analysis, risk mitigations identified were verified for effectiveness in accordance with relevant standards and established protocols with pre-determined acceptance criteria. Testing verified all acceptance criteria were met.

9. Conclusion

The ADVIA® Chemistry Enzymatic Hemoglobin A1c (A1c_E) Assay modified device is substantially equivalent to the predicate in intended use/indications for use, fundamental technology, principle of operation, formulation, and method parameters related to sample and reagent volume, mix speed, wavelengths, and read times.

The change to the device was to extend the low end of the measuring range for total hemoglobin (tHb). The change is to Siemens Healthcare Diagnostics Inc. own device. Performance data were needed to evaluate the change. Risk analysis and verification activities were performed as part of design control activities.

The risks identified to the assay Special Controls set forth in 21 CFR 862.1373(b) and the device modification were acceptable and mitigations are effective. The verification study of linearity was done in accordance with the CLSI standard recognized by the FDA. This study along with other verification activities demonstrate equivalent performance to the predicate and effective risk mitigations. The studies met pre-determined acceptance criteria.

Results from design control activities including the risk analysis and the verification activities support substantial equivalence between the change device and the predicate. The changes to not impact the safety or effectiveness of the device.

END OF SUMMARY