April 13, 2020

Siemens Healthcare Diagnostics Inc.
Mey Lyn Vasquez
Regulatory Clinical Affairs Specialist
511 Benedict Ave.
Tarrytown, NY 10591

Re: K200215
Trade/Device Name: ADVIA Centaur CEA Assay
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: DHX
Dated: January 27, 2020
Received: January 28, 2020

Dear Mey Lyn Vasquez:

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,

Carolina Kagan
Acting Chief
Division of Immunology
and Hematology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k200215

Device Name
ADVIA Centaur® CEA assay

Indications for Use *(Describe)*
For in vitro diagnostic use in the quantitative measurement of carcinoembryonic antigen (CEA) in serum and plasma (EDTA and lithium heparin) to aid in the management of cancer patients in whom changing concentrations of CEA are observed using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

510(k) Summary of Safety and Effectiveness

Introduction: According to the requirements of SMDA 1990 and 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: ____k200215_____

1. APPLICANT

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue,
Tarrytown, NY 10591 USA

Contact: Mey Vasquez
Regulatory Clinical Affairs Specialist
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Date Prepared: April 09, 2020

2. Regulatory Information

Assay

Trade Name	ADVIA Centaur® CEA assay
Device	system, test, carcinoembryonic antigen
Regulation Description	Tumor-associated antigen immunological test system
FDA Classification	Class II
Review Panel	Immunology
Product Code	DHX
Regulation Number	21 CFR 866.6010

3. PREDICATE DEVICE

Assay

Name of Device: ADVIA Centaur® CEA assay

510 (k): K981478

4. DEVICE DESCRIPTION

The assay reagents come in the following configurations:

Contents	Number of Tests
5 ReadyPack primary reagent packs containing ADVIA Centaur CEA Lite Reagent and Solid Phase ADVIA Centaur CEA Master Curve card	500
1 ReadyPack primary reagent pack containing ADVIA Centaur CEA Lite Reagent and Solid Phase ADVIA Centaur CEA Master Curve card	100

The ReadyPack consists of the following:

ADVIA Centaur® CEA ReadyPack® primary reagent pack; Lite Reagent
5.0 mL/reagent pack polyclonal rabbit anti-CEA antibody (~400 ng/mL) labeled with acridinium ester in phosphate buffered saline with protein stabilizers, sodium azide (0.12%), and preservatives

ADVIA Centaur® CEA ReadyPack® primary reagent pack; Solid Phase Reagent
25.0 mL/reagent pack monoclonal mouse anti-CEA antibody (~120 µg/mL) covalently coupled to paramagnetic particles in phosphate buffered saline with protein stabilizers, sodium azide (0.11%), and preservatives

ADVIA Centaur® CEA ReadyPack® ancillary reagent pack; CEA Diluent
5.0 mL/reagent pack bicine buffer, gelatin, and BSA with preservatives and sodium azide (0.1%)

ADVIA Centaur® CEA Diluent
10.0 mL/reagent vial bicine buffer, gelatin, and BSA with preservatives and sodium azide (0.1%)

5. INDICATIONS FOR USE

For *in vitro* diagnostic use in the quantitative measurement of carcinoembryonic antigen (CEA) in serum and plasma (EDTA and lithium heparin) to aid in the management of cancer patients in whom changing concentrations of CEA are observed using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.

6. INTENDED USE

Same as Indications for Use

7. Purpose of the Submission

The purpose of this submission is for the addition of plasma (EDTA and lithium heparin) sample claim for the ADVIA Centaur® CEA assay.

8. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table demonstrates substantial equivalence between the ADVIA Centaur® CEA assay (Candidate Device) that has modified Instructions for Use (Package Inserts) with the addition of the plasma (EDTA and lithium) sample claim and the currently marketed ADVIA Centaur® CEA assay (Predicate Device) that was cleared under 510(k) K981478.

Table 1: Substantial Equivalence Comparison

Assay		
Item	**Predicate Device**	**Candidate Device**
	ADVIA Centaur® CEA assay	ADVIA Centaur® CEA assay
Intended Use	For *in vitro* diagnostic use in the quantitative measurement of carcinoembryonic antigen (CEA) in serum to aid in the management of cancer patients in whom changing concentrations of CEA are observed using the ADVIA Centaur®, ADVIA Centaur XP, and ADVIA Centaur XPT systems.	For *in vitro* diagnostic use in the quantitative measurement of carcinoembryonic antigen (CEA) in serum and plasma (EDTA and lithium heparin) to aid in the management of cancer patients in whom changing concentrations of CEA are observed using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.
Measurement	Quantitative	Same
Assay Range	0.5–100 ng/mL (µg/L)	2.00-100 ng/mL (µg/L)
Assay Principle	Sandwich immunoassay	Same
Technology	Direct chemiluminescent	Same
Sample Type	Serum	Serum or plasma (EDTA or lithium heparin)
Sample Volume	50 µL	Same
Reagent Volume	50 µL of Lite Reagent and 250 µL of Solid Phase	Same
Incubation Time	7.5 minutes at 37°C.	Same
Standardization	The ADVIA Centaur CEA assay is traceable to an internal standard manufactured using highly purified material. Assigned values for calibrators are traceable to this standardization.	Same
Calibration	2-point	Same
Calibrators	ADVIA Centaur Calibrator D	Same

Assay		
Item	**Predicate Device**	**Candidate Device**
	ADVIA Centaur® CEA assay	ADVIA Centaur® CEA assay
Number of Calibrator Levels	Two levels	Same
Controls	Commercial Controls	Same
Number of Control Levels	2	Same

9. PERFORMANCE CHARACTERISTICS DATA

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[11]

Limit of Blank (LoB)	0.50 ng/mL (µg/L)
Limit of Detection (LoD)	1.00 ng/mL (µg/L)
Limit of Quantitation (LoQ)	2.00 ng/mL (µg/L)

The LoB corresponds to the highest measurement likely to be observed for a blank sample with a probability of 95%.

The LoD corresponds to the lowest concentration of carcinoembryonic antigen that can be detected with a probability of 95%.

The LoQ corresponds to the lowest amount of carcinoembryonic antigen in a sample at which the within laboratory CV is ≤ 20%.

Precision

Cleared under premarket submission k981478

Method Comparison

Method comparison data and regression analysis was revised in k200215.

Accuracy / Method Comparison

For 201 samples in the range of 2.00 to 78.93 ng/mL (µg/L), the relationship between the ADVIA Centaur CEA assay and the ACS:180 CEA assay is described by the equation:

ADVIA Centaur CEA = 0.97 (ACS:180 CEA) + 0.11 ng/mL

Correlation coefficient (r) = 1.00

Specimen Equivalence

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3. The following results were obtained:

Tube (y) vs. Serum (x)	N [a]	Sample Interval	Slope	Intercept	r [b]
Dipotassium EDTA plasma	64	2.08–97.10 ng/mL (µg/L)	0.95	0.20 ng/mL (µg/L)	1.00
Lithium heparin plasma	46	2.11–97.10 ng/mL (µg/L)	0.99	0.19 ng/mL (µg/L)	1.00

a Number of samples tested.
b Correlation coefficient.

The assay is designed to have a slope of 0.90–1.10 for alternate tube types versus serum.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Interference testing was performed in accordance with CLSI Document EP07-ed3. The following results were obtained:

Substance	Substance Test Concentration	Analyte Concentration ng/mL (µg/L)	Bias (%)
Dipotassium EDTA	9.0 mg/mL	5.78	-0.3
		55.62	4.6
Heparin	75 U/mL	5.83	-0.6
		61.23	0.9

Assay results obtained at individual laboratories may vary from the data presented.

Expected Values

Cleared under premarket submission k981478

X. CONCLUSION

Comparative testing of the ADVIA Centaur® CEA assay is substantially equivalent in principle and performance to the Predicate Device – ADVIA Centaur® CEA assay cleared under 510(k) K981478.