July 16, 2021

Siemens Healthcare Diagnostics, Inc.
Anoop Joy
Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, New York 10591

Re: K193397
Trade/Device Name: ADVIA Centaur Digoxin assay
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin Test System
Regulatory Class: Class II
Product Code: KXT
Dated: October 16, 2020
Received: October 19, 2020

Dear Anoop Joy:

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)*
k193397

Device Name
ADVIA Centaur® Digoxin assay

Indications for Use *(Describe)*
For in vitro diagnostic use in the quantitative determination of digoxin in serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP systems.

Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

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.

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510(k) Summary of Safety and Effectiveness

ADVIA Centaur® Digoxin assay

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.

The assigned 510(k) Number: k193397.

I. APPLICANT

Siemens Healthcare Diagnostics Inc.
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Tarrytown, NY 10591 USA

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Date Prepared: July 16, 2021

II. Regulatory Information

Name of Device: ADVIA Centaur® Digoxin assay
Classification: Class II
Regulation Section: 21 CFR § 862.3320
Product Code: KXT
Panel: Toxicology

III. PREDICATE DEVICE

Name of Device: ADVIA Centaur® Digoxin assay
510 (k): K931213

IV. DEVICE DESCRIPTION

The ADVIA Centaur Digoxin assay reagents come in the following configurations:

Contents	Number of Tests
5 ReadyPack primary reagent packs containing ADVIA Centaur DIG Lite Reagent and Solid Phase, ADVIA Centaur DIG Master Curve card	250
1 ReadyPack primary reagent pack containing ADVIA Centaur DIG Lite Reagent and Solid Phase, ADVIA Centaur DIG Master Curve card	50

The ReadyPack consists of the following:

ADVIA Centaur DIG ReadyPack® primary reagent pack; Lite Reagent
2.5 mL/reagent pack monoclonal mouse anti-digoxin antibody (~26.4 ng/mL) labeled with acridinium ester in protein buffered saline with sodium azide (0.11%) and preservatives.

ADVIA Centaur DIG ReadyPack primary reagent pack; Solid Phase Reagent
12.5 mL/reagent pack digitoxin (~2 ng/mL) covalently coupled to paramagnetic particles in protein buffered saline with sodium azide (0.11%) and preservatives.

V. INTENDED USE

For in vitro diagnostic use in the quantitative determination of digoxin in serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP systems.

Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

VI. INDICATIONS FOR USE

Same as Intended use

VII. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table provides a comparison between the predicate and candidate device.

Table 1: *Substantial Equivalence Comparison*

Item	Predicate Device	Candidate Device (Modified Device)
	ADVIA Centaur® Digoxin assay	ADVIA Centaur® Digoxin assay
Intended Use	For in vitro diagnostic use in the quantitative determination of digoxin in serum using the ADVIA Centaur®, ADVIA Centaur XP, and ADVIA Centaur XPT systems.	For in vitro diagnostic use in the quantitative determination of digoxin in serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP systems. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.
Measurement	Quantitative	Same
Assay Range	0.1–5.0 ng/mL	same
Assay Principle	competitive immunoassay	Same
Technology	Direct chemiluminescent	Same
Sample Type	Serum	Serum and plasma (EDTA and lithium heparin)
Sample Volume	50 µL	same
Reagent Volume	50 µL of Lite Reagent and 250 µL of Solid Phase	same
Incubation Time	Lite Reagent: 5.0 minutes at 37°C Solid Reagent: 2.5 minutes at 37°C.	same
Standardization	Traceable to an internal standard manufactured using U.S.P. (United States Pharmacopeia) material	Same
Calibration	2-point	Same
Calibrators	ADVIA Centaur Calibrator B	Same
Number of Calibrator Levels	Two levels	Same
Controls	Commercial Controls	Same
Detection Antibody	monoclonal mouse anti-digoxin antibody labeled with acridinium ester	Same
Capture Antibody	digitoxin covalently coupled to paramagnetic particles	Same

VIII. PERFORMANCE CHARACTERISTICS DATA

Addition of plasma sample type claim was demonstrated by performing specimen equivalency studies, precision studies and interference studies using EDTA and

Heparin. Since the assay principle, design or formulation has not changed from original device (K931213), the analytical performance data previously reviewed for the ADVIA Centaur® Digoxin assay continues to apply to this assay.

Specimen Equivalency

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

Tube (y) vs. Serum (x)	Regression Equation	Sample Interval	N [a]	r [b]
Dipotassium EDTA plasma	y = 1.02x - 0.02 ng/mL (y = 1.02x - 0.03 nmol/L)	0.14–4.81 ng/mL (0.18–6.16 nmol/L)	51	0.996
Lithium heparin plasma	y = 1.06x - 0.03 ng/mL (y = 1.06x - 0.04 nmol/L)	0.14–4.88 ng/mL (0.18–6.25 nmol/L)	50	0.990

[a] Number of samples tested.
[b] Correlation coefficient.

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 (nmol/L)	Bias (%)
Canrenone	1000 ng/mL	1.11 (1.42)	2.7
		2.12 (2.71)	-0.5
Dipotassium EDTA	9.0 mg/mL	0.91 (1.16)	-0.4
		3.12 (3.99)	-1.1
Heparin	75 U/mL	0.61 (0.78)	8.9
		3.66 (4.68)	-1.7
Potassium Canrenoate	1000 ng/mL	1.07 (1.37)	2.8
		2.08 (2.66)	-1.0
Spironolactone	1000 ng/mL	1.04 (1.33)	1.0
		2.00 (2.56)	2.5

X. CONCLUSION

Comparative testing of the modified ADVIA Centaur® Digoxin assay is substantially equivalent in principle and performance to the Predicate Device - *ADVIA Centaur® Digoxin assay* cleared under 510(k) K931213.