March 29, 2018

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

Re: k172322
Trade/Device Name: Atellica IM Total hCG (ThCG)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: February 20, 2018
Received: February 21, 2018

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. 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); 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k172322

Device Name
Atellica IM Total hCG (ThCG)

Indications for Use *(Describe)*
The Atellica IM Total hCG (ThCG) assay is for in vitro diagnostic use in the quantitative determination of human chorionic gonadotropin (hCG) in human serum using the Atellica IM Analyzer.

The Atellica IM ThCG assay is intended for use as an aid in the early detection of pregnancy.

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

Atellica IM Total hCG (ThCG)

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: k172322

I. APPLICANT

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Date Prepared: March 28, 2018

II. Regulatory Information

Assay

Name of Device: Atellica IM Total hCG (ThCG)
Classification: Class II
Regulation Section: 21 CFR § 862.1155
Product Code: JHI
Panel: Clinical Chemistry

III. PREDICATE DEVICE

Assay

Name of Device: ADVIA Centaur® Total hCG assay
510 (k): k925277

IV. DEVICE DESCRIPTION

The Atellica IM ThCG Assay reagents come in the following configurations:

Contents	Number of Tests
1 ReadyPack primary reagent pack containing Atellica IM ThCG Lite Reagent and Solid Phase Atellica IM ThCG master curve and test definition	90
5 ReadyPack primary reagent packs containing Atellica IM ThCG Lite Reagent and Solid Phase Atellica IM ThCG master curve and test definition	450

The ReadyPack consists of the following:

Atellica IM ThCG ReadyPack® primary reagent pack Lite Reagent
5.0 mL/reagent pack Goat polyclonal anti-hCG antibody (~0.1 µg/mL) labeled with acridinium ester in buffered saline; sodium azide (0.1%); preservatives

Solid Phase
22.5 mL/reagent pack Mouse monoclonal anti-hCG antibody (~0.02 mg/mL) covalently coupled to paramagnetic particles in buffered saline; sodium azide (0.1%); preservatives.

Atellica IM ThCG DIL ReadyPack ancillary reagent pack
25.0 mL/pack Buffered heat-treated equine serum; EDTA; sodium azide (< 0.1%); preservatives

Atellica IM ThCG DIL
50.0 mL/vial Buffered heat-treated equine serum; EDTA; sodium azide (< 0.1%); preservatives

V. INDICATIONS FOR USE

The Atellica IM Total β-hCG (ThCG) assay is for in vitro diagnostic use in the quantitative determination of human gonadotropin (hCG) in human serum using the Atellica IM Analyzer.

The Atellica IM ThCG assay is intended for use as an aid in the early detection of pregnancy.

VI. INTENDED USE

Same as Indications for 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*

Assay		
Item	**Predicate Device**	**Candidate Device**
	ADVIA Centaur Total hCG	Atellica IM Total hCG
Intended Use	For in vitro diagnostic use in the quantitative determination of human chorionic gonadotropin (hCG) in serum. The results obtained from hCG specimens are used as an aid in the assessment of pregnancy status. This assay detects the intact hCG molecule and free beta-subunits of the hCG molecule.	The Atellica IM Total β-hCG (ThCG) assay is for in vitro diagnostic use in the quantitative determination of human gonadotropin (hCG) in human serum using the Atellica IM Analyzer. The Atellica IM ThCG assay is intended for use as an aid in the early detection of pregnancy.
Measurement	Quantitative	Same
Assay Range	2.0–1000 mIU/mL (IU/L)	2.6–1000 mIU/mL (IU/L)
Assay Principle	Sandwich immunoassay	Same
Technology	Direct chemiluminescent	Same
Sample Type	Serum	Same
Sample Volume	50 µL	25 µL
Reagent Volume	100 µL of Lite Reagent and 450 µL of Solid Phase	50 µL of Lite Reagent and 225 µL of Solid Phase
Incubation Time	7.5 minutes at 37°C.	8 minutes at 37°C
Standardization	Standardized against the World Health Organization (WHO) 4th IS 75/589 reference material. Assigned values for calibrators are traceable to this standardization.	Same
Calibration	2-point	Same
Calibrators	ADVIA Centaur Calibrator B	Atellica IM CAL B
Number of Calibrator Levels	Two levels	Same
Controls	Commercial Controls	Same
Number of Control Levels	2	Same
Detection Antibody	Goat polyclonal anti-hCG antibody labeled with acridinium ester	Same
Capture Antibody	Mouse monoclonal anti-hCG antibody covalently coupled to paramagnetic	Same

	particles	
Expected Values	2–4 weeks 39.1–8388 (mIU/mL) (IU/L) 5–6 weeks 861–88,769 6–8 weeks 8636–218,085 8–10 weeks 18,700–244,467 10–12 weeks 23,143–181,899 13–27 weeks 6303–97,171 28–40 weeks 4360–74,883	The 2.5 and 97.5 percentiles of the concentration values were considered the expected value range of the Atellica IM ThCG assay. The expected value range of non-pregnant females was 1.5–4.2 mIU/mL (IU/L) and the postmenopausal female population was 1.8–10.1 mIU/mL (IU/L)

VIII. PERFORMANCE CHARACTERISTICS DATA

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17‑A2.

The LoB corresponds to the highest measurement result that is likely to be observed for a blank sample. The LoB of the Atellica IM ThCG assay is 1.5 mIU/mL (IU/L).

The LoD corresponds to the lowest concentration of hCG that can be detected with a probability of 95%. The LoD for the Atellica IM ThCG assay is 1.7 mIU/mL (IU/L), and was determined using 601 determinations, with 300 blank and 301 low-level replicates, and an LoB of 1.5 mIU/mL (IU/L).

The LoQ corresponds to the lowest amount of hCG in a sample at which the percent total error is 30%. The LoQ of the Atellica IM ThCG assay is 2.6 mIU/mL (IU/L), and was determined using multiple samples prepared from the World Health Organization (WHO) human chorionic gonadotropin reference material (NIBSC code: 99/688) in the interval 1.9–6.7 mIU/mL (IU/L). All samples were assayed in replicates of 5 in each of 2 runs per day using 2 reagent lots, over a period of 5 days

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed in duplicate in 2 runs per day for 20 days using two reagent lots on each of two Atellica IM analyzers. The following results were obtained:

Sample	N[a]	Mean mIU/mL (IU/L)	Repeatability		Between Run		Between Day		Within-Lab	
			SD[b] mIU/mL (IU/L)	%CV[c]	SD mIU/mL (IU/L)	%CV[c]	SD[b] mIU/mL (IU/L)	%CV[c]	SD[b] mIU/mL (IU/L)	%CV[c]
Serum 1	320	2.4	0.2	8.8	0.1	3.3	0.1	4.7	0.3	10.5
Serum 2	320	12.6	0.4	2.8	0.2	1.6	0.1	1.0	0.4	3.4
Serum 3	320	782.0	14.0	1.8	6.9	0.9	6.7	0.9	17.0	2.2
Control 1	320	6.8	0.3	4.5	0.0	0.3	0.2	3.0	0.4	5.5
Control 2	320	23.4	0.6	2.6	0.4	1.7	0.4	1.6	0.8	3.5
Control 3	320	202.1	3.6	1.8	2.4	1.2	3.4	1.7	5.5	2.7

[a] Number of samples tested.
[b] Standard deviation.
[c] Coefficient of variation.

Method Comparison

The Atellica IM ThCG assay is designed to have a correlation coefficient of ≥ 0.95 and a slope of 1.0 ±0.10 compared to the ADVIA Centaur Total hCG assay. Assay comparison was determined using the weighted Deming regression model in accordance with CLSI Document EP09-A3. The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	ADVIA Centaur Total hCG	y = 0.94x + 0.23 mIU/mL (IU/L)	2.4–947.7 mIU/mL (IU/L)	115	1.00

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

Interferences

Interference testing was performed in accordance with CLSI Document EP07‑A2 using the Atellica IM Analyzer.

The following substances were added to serum samples containing different concentrations of hCG. Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Analyte results should not be corrected based on the bias.

Substance	Substance Test Concentration	Analyte Concentration mIU/mL (IU/L)	Bias (%)
Acetaminophen	20 mg/dL	5.7	0.9
	20 mg/dL	495.3	2.9
Acetylsalicylic acid	65 mg/dL	5.4	7.3
	65 mg/dL	502.1	-0.8
Atropine	20 mg/dL	5.7	-4.7
	20 mg/dL	503.6	-0.9
Caffeine	308 µmol/L	5.6	5.4
	308 µmol/L	511.9	-1.8
EDTA	3.4 µmol/L	5.5	5.9
	3.4 µmol/L	508.9	-2.2
Ethanol	100 mg/dL	6.0	-6.6
	100 mg/dL	506.2	2.0
Gentisic acid	117 µmol/L	6.2	-5.8
	117 µmol/L	507.1	-2.7
Heparin	7200 IU/dL	5.5	-2.3
	7200 IU/dL	491.3	1.1
Human Serum Albumin	6 g/dL	6.0	-0.3
	6 g/dL	511.8	1.3
Ibuprofen	50 mg/dL	5.5	6.5
	50 mg/dL	490.1	-2.7

Hemolysis, Icterus, and Lipemia (HIL): The Atellica IM ThCG assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances were tested at the levels indicated in the table below. Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent.

Substance	Substance Test Concentration	Analyte Concentration mIU/mL (IU/L)	Bias (%)
Hemoglobin	1000 mg/dL (0.62 mmol/L)	5.6	8.9
	1000 mg/dL (0.62 mmol/L)	501.7	-1.2
Bilirubin, conjugated	40 mg/dL (681 µmol/L)	6.1	-0.3
	40 mg/dL (681 µmol/L)	530.3	-1.8
Bilirubin, unconjugated	40 mg/dL (681 µmol/L)	6.0	0.3
	40 mg/dL (681 µmol/L)	520.8	-1.8
Lipemia (Intralipid®)	3000 mg/dL (34 mmol/L)	6.1	2.0
	3000 mg/dL (34 mmol/L)	458.8	2.4

Expected Values

Data were obtained on 366 serum samples from 192 apparently healthy non-pregnant females and 174 apparently healthy postmenopausal females. The expected value range of non-pregnant females was 1.5–4.2 mIU/mL (IU/L) and the postmenopausal female population was 1.8–10.1 mIU/mL (IU/L), as shown in the table below.

Sample Category	N[a]	Median mIU/mL (IU/L)	Reference Interval mIU/mL (IU/L) 2.5–97.5 Percentile
Non-Pregnant Females (Age: 17–54)	192	2.0	1.5–4.2
Postmenopausal Females Age: ≥ 41	174	3.9	1.8–10.1

[a] Number of samples.

X. CONCLUSION

Comparative testing of the Atellica IM ThCG Assay is substantially equivalent in principle and performance to the Predicate Device - *ADVIA Centaur® Total hCG* assay cleared under 510(k) K925277.