February 6, 2026

Siemens Healthcare Diagnostics, Inc.
Kelly Scuderi
Regulatory Affairs Professional
511 Benedict Ave
Tarrytown, New York 10591

Re: K251543
Trade/Device Name: Atellica® IM TSH3-Ultra II (TSH3ULII)
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid Stimulating Hormone Test System
Regulatory Class: Class II
Product Code: JLW
Dated: Dec 29, 2025
Received: Dec 29, 2025

Dear Kelly Scuderi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251543

Device Name
Atellica® IM TSH3-Ultra II (TSH3ULII)

Indications for Use *(Describe)*
The Atellica® IM TSH3-Ultra II (TSH3ULII) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

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

510(k) Summary of Safety and Effectiveness

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 is: K251543

1. Applicant

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

Contact: Kelly Scuderi
Title: Regulatory Affairs Professional
E-mail: kelly.scuderi@siemens-healthineers.com
Phone: 781-856-6516

Date of Preparation: December 29, 2025

2. Device

Regulatory Information

Device Name:	Atellica® IM TSH3-Ultra II (TSH3ULII)
Classification Name:	Thyroid stimulating hormone test system
Regulation Number:	21 CFR 862.1690
Classification:	Class II
Product Code:	JLW
Review Panel:	Clinical Chemistry

3. Predicate Device

The predicate device, ADVIA Centaur® TSH3-Ultra II (TSH3ULII) manufactured by Siemens Healthcare Diagnostics, Inc, Tarrytown, NY USA, was cleared by the FDA under K233050.

4. Device Description

This assay is a third-generation assay that employs anti-FITC monoclonal antibody covalently bound to paramagnetic particles, an FITC-labeled anti-TSH capture mouse monoclonal antibody, and a tracer consisting of a proprietary acridinium ester and an anti-TSH mouse monoclonal antibody conjugated to bovine serum albumin (BSA) for chemiluminescent detection.

5. Intended Use

The Atellica® IM TSH3-Ultra II (TSH3ULII) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma

(EDTA and lithium heparin) using the Atellica® IM Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

6. Indications for Use

Same as Intended use.

7. Comparison of Technological Characteristics with the Predicate Device

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

Attribute	**Candidate Device:** Atellica IM TSH3-Ultra II	**Predicate Device**: ADVIA Centaur TSH3-Ultra II
Intended Use / Indications for Use	The Atellica® IM TSH3-Ultra II (TSH3ULII) assay is for *in vitro* diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.	The ADVIA Centaur® TSH3-Ultra II (TSH3ULII) assay is for *in vitro* diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP system. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.
Analyte	TSH	Same
Automated	Automated assay	Same
Measurement	Quantitative	Same
Sample Type	Human serum and plasma	Same
Detection Limit	LoQ: ≤ 0.008 µIU/mL (mIU/L)	LoQ: ≤ 0.010 µIU/mL (mIU/L)
Assay Range	0.008 – 150.000 µIU/mL (mIU/L)	0.010 – 150.000 µIU/mL (mIU/L)
Operating Principle	Immunologic sandwich	Same
Technology	Direct chemiluminescent	Same
Lite Reagent Antibody	Mouse monoclonal anti-TSH antibody BSA conjugate labeled with acridinium ester	Same
Solid Phase Antibody	FITC-labeled mouse monoclonal anti-TSH antibody and mouse monoclonal anti-fluorescein antibody linked to paramagnetic particles	Same
Ancillary Antibody	FITC conjugated to mouse monoclonal anti-TSH antibody	Same
Sample Volume	75 µL	100 µL
Calibrator	After reconstitution, TSH (human); buffer; equine serum; sodium azide (< 0.1%); stabilizers; preservatives	Same
Number of Calibrators	2 levels (low and high)	Same
Calibrators Packaging	Provided with reagent kit	Same
Use of Controls	Yes (recommended)	Same

Traceability	Traceable to the World Health Organization (WHO) 3rd International Reference Preparation for human TSH (IRP 81/565).	Same

8. Performance Characteristics Data

Detection Capability

Detection capability was determined using the Atellica IM Analyzer in accordance with CLSI Document EP17-A2. The following results are representative of the performance of the assay.

Detection Capability	Atellica IM Analyzer Result
Limit of Blank (LoB)	0.001 µIU/mL (mIU/L)
Limit of Detection (LoD)	0.003 µIU/mL (mIU/L)
Limit of Quantitation (LoQ)	0.004 µIU/mL (mIU/L)

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

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

The LoQ corresponds to the lowest analyte concentration at which the within laboratory CV s 20.0%.

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed in replicates of 2 with 2 runs per day using a 20-day protocol.

The following results are representative of the performance of the assay:

Sample	N[a]	Mean µIU/mL (mIU/L)	Repeatability SD[b] µIU/mL (mIU/L)	Repeatability CV[c] (%)	Within-Laboratory Precision SD µIU/mL (mIU/L)	Within-Laboratory Precision CV (%)
Serum A	80	0.086	0.0018	2.1	0.0027	3.2
Serum B	80	0.194	0.0043	2.2	0.0050	2.6
Serum C	80	0.496	0.0103	2.1	0.0156	3.1
Serum D	80	4.739	0.0974	2.1	0.1328	2.8
Serum E	80	48.040	1.2643	2.6	1.7163	3.6
Serum F	80	98.207	2.4514	2.5	2.8295	2.9
Plasma, lithium heparin A	80	0.096	0.0018	1.8	0.0030	3.1
Plasma, lithium heparin B	80	0.513	0.0112	2.2	0.0168	3.3
Plasma, lithium heparin C	80	4.802	0.1108	2.3	0.1700	3.5
Plasma, lithium heparin D	80	52.769	1.1208	2.1	1.4833	2.8
Plasma, lithium heparin E	80	93.097	3.1793	3.4	4.2404	4.6
Control 1	80	0.103	0.0016	1.6	0.0022	2.2
Control 2	80	0.522	0.0071	1.4	0.0121	2.3
Control 3	80	4.800	0.0505	1.1	0.1173	2.4
Control 4	80	47.803	0.7748	1.6	1.0919	2.3
Control 5	80	101.770	2.1680	2.1	2.9022	2.9

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

Reproducibility

Reproducibility was determined in accordance with CLSI Document EP05-A3. Testing was performed using 3 instruments and 3 reagent lots. Samples were assayed in replicates of 5 with 1 run per day using a 5-day protocol (225 measurements per sample).

The following results are representative of the performance of the assay:

Sample	Mean µIU/mL (mIU/L)	Repeatability SD[a] µIU/mL (mIU/L)	Repeatability CV[b] (%)	Between Day SD µIU/mL (mIU/L)	Between Day CV (%)	Between Lot SD µIU/mL (mIU/L)	Between Lot CV (%)	Between Instrument SD µIU/mL (mIU/L)	Between Instrument CV (%)	Reproducibility SD µIU/mL (mIU/L)	Reproducibility CV (%)
Serum A	0.087	0.002	2.12	0.001	1.30	0.003	3.44	0.001	1.26	0.004	4.43
Serum B	0.172	0.004	2.12	0.002	1.42	0.005	2.82	0.002	0.92	0.007	3.91
Serum C	0.449	0.009	2.04	0.004	0.92	0.011	2.52	0.003	0.58	0.015	3.42
Serum D	4.450	0.094	2.12	0.054	1.21	0.067	1.50	0.044	0.98	0.135	3.03
Serum E	53.797	1.160	2.16	0.672	1.25	1.042	1.94	0.614	1.14	1.805	3.36
Serum F	100.021	2.250	2.25	1.789	1.79	3.066	3.06	0.590	0.59	4.244	4.24
Plasma A	0.090	0.002	2.23	0.001	1.07	0.003	3.54	0.002	1.86	0.004	4.70
Plasma B	0.422	0.009	2.13	0.004	1.06	0.010	2.42	0.007	1.54	0.016	3.73
Plasma C	4.293	0.080	1.86	0.082	1.91	0.065	1.52	0.023	0.54	0.134	3.12
Plasma D	47.836	1.052	2.20	0.789	1.65	0.768	1.61	0.731	1.53	1.689	3.53
Plasma E	98.087	2.139	2.18	2.512	2.56	2.877	2.93	1.824	1.86	4.743	4.84
Control 1	0.102	0.002	2.06	0.001	1.12	0.004	3.71	0.001	0.69	0.005	4.44
Control 2	0.506	0.008	1.63	0.005	1.08	0.013	2.57	0.003	0.59	0.017	3.28
Control 3	4.627	0.082	1.78	0.045	0.96	0.079	1.70	0.024	0.52	0.125	2.69
Control 4	45.957	0.854	1.86	0.586	1.28	0.725	1.58	0.000	0.00	1.264	2.75
Control 5	97.579	2.007	2.06	1.228	1.26	2.508	2.57	0.000	0.00	3.439	3.52

[a] Standard deviation.
[b] Coefficient of variation.

Assay Comparison

Assay comparison was determined with the Passing-Bablok regression model in accordance with CLSI Document EP09c-ed3.

Agreement of the assays may vary depending on the study design, comparative assay, and population tested.

Sample	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Atellica IM TSH3-UL assay using the Atellica IM Analyzer	y = 0.97x - 0.006 µIU/mL	0.011–147.2 µIU/mL	323	0.998

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

Specimen Equivalency

Specimen equivalency was determined with the Passing-Bablok regression model using the ADVIA Centaur XP system in accordance with CLSI Document EP09c-ed3.

Agreement of the specimen types may vary depending on the study design and population tested.

Tube (y) vs. Serum (x)	Regression Equation	Sample Interval	N[a]	r[b]
Plasma, EDTA	y = 0.99x - 0.017 µIU/mL	0.008–147.8 µIU/mL	53	0.999
Plasma, lithium heparin	y = 1.01x - 0.034 µIU/mL	0.115–135.9 µIU/mL	57	0.990

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

Interferences

Hemolysis, Icterus, Lipemia (HIL):

Interference testing was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.

The following substances do not interfere with the assay when present in serum at the concentrations indicated. Bias due to these substances does not exceed 10% at a TSH concentration of approximately 0.900 µIU/mL (mIU/L) and 8.000 µIU/mL (mIU/L).

Substance	Substance Test Concentration
Hemoglobin	500 mg/dL (5.00 g/L)
Bilirubin, conjugated	40 mg/dL (474 µmol/L)
Bilirubin, unconjugated	40 mg/dL (684 µmol/L)
Lipemia (Intralipid)	1000 mg/dL (11.3 mmol/L)

Other Substances:

Interference testing was performed using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.

The following substances do not interfere with the assay when present in serum at the concentrations indicated. Bias due to these substances does not exceed 10% at TSH concentrations of approximately 0.900 µIU/mL (mIU/L) and 8.000 µIU/mL (mIU/L).

Substance	Substance Test Concentration	Substance	Substance Test Concentration
Acetaminophen	15.6 mg/dL (1033 µmol/L)	Liothyronine	0.0075 mg/dL (0.116 µmol/L)
Acetylsalicylic acid	3.0 mg/dL (167 µmol/L)	Methimazole	8.0 mg/dL (701 µmol/L)
Ampicillin	7.5 mg/dL (215 µmol/L)	Methyldopa	2.25 mg/dL (107 µmol/L)
Ascorbic Acid	5.25 mg/dL (298 µmol/L)	Metronidazole	12.3 mg/dL (719 µmol/L)
Biotin	0.35 mg/dL (14.3 µmol/L)	N-Acetylcysteine	15.0 mg/dL (920 µmol/L)
Carbimazole	3.0 mg/dL (161 µmol/L)	Octreotide	0.03 mg/dL (0.294 µmol/L)
Cefoxitin	495 mg/dL (11583 µmol/L)	Phenylbutazone	32.1 mg/dL (1040 µmol/L)
Cholesterol	400 mg/dL (10.3 mmol/L)	Propranolol	24 mg/dL (926 µmol/L)
Cyclosporine	0.18 mg/dL (1.50 µmol/L)	Propylthiouracil	30 mg/dL (1762 µmol/L)
Doxycycline	1.8 mg/dL (40.5 µmol/L)	Rheumatoid Factor	1500 IU/mL
Heparin	7500 U/dL	Rifampicin	4.8 mg/dL (58.6 µmol/L)
Ibuprofen	21.9 mg/dL (1062 µmol/L)	Theophylline	6.0 mg/dL (333 µmol/L)
Levodopa	0.75 mg/dL (38.0 µmol/L)	Total Protein	15 g/dL (150 g/L)
Levothyroxine	0.0429 mg/dL (0.552 µmol/L)		

Cross-Reactivity

Cross-reactivity was determined using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3. Cross-reactivity of samples spiked with various substances does not exceed 5% at TSH concentrations of approximately 0.400 µIU/mL (mIU/L), 5.00 µIU/mL (mIU/L), 17.00 µIU/mL (mIU/L), and 90.00 µIU/mL (mIU/L).

Substance	Substance Test Concentration
hCG	200,000 mIU/mL
FSH	1500 mIU/mL
LH	600 mIU/mL

Linearity

Linearity testing was performed in accordance with CLSI Document EP06-ed2 using the Atellica IM Analyzer.

The assay is linear for the measuring interval of 0.008–150.000 µIU/mL (mIU/L).

High-Dose Hook Effect

High TSH concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with TSH concentrations above the measuring interval and as high as 3000 µIU/mL will report > 150 µIU/mL (mIU/L).

Standardization

The assay standardization is traceable to the World Health Organization (WHO) 3rd International Reference Preparation for human TSH (IRP 81/565).

Assigned values for calibrators are traceable to this standardization.

9. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.