January 5, 2026

Siemens Healthcare Diagnostics, Inc.
Kira Gordon
Sr. Regulatory Affairs Specialist
511 Benedict Ave
Tarrytown, New York 10591

Re: K251630
Trade/Device Name: Atellica IM total PSA II (tPSAII)
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: LTJ
Dated: November 20, 2025
Received: November 20, 2025

Dear Kira Gordon:

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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology 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)*
K251630

Device Name
Atellica IM total PSA II (tPSAII)

Indications for Use *(Describe)*
Atellica IM total PSA II (tPSAII) assay is for in vitro diagnostic use in the quantitative measurement of total prostate-specific antigen (PSA) in human serum and plasma (EDTA and lithium-heparin) using the Atellica IM Analyzer.

This assay is indicated as an aid in the detection of prostate cancer in conjunction with a digital rectal exam (DRE) in men aged 50 years and older. Prostate biopsy is required for diagnosis of prostate cancer. This assay is further indicated as an aid in the management (monitoring) of patients with prostate cancer

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.

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510(k) Summary

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

The assigned 510(k) Number is: K251630

1. Date Prepared

November 14, 2025

2. Applicant Information

Contact: Kira Gordon
Sr. Regulatory Affairs Specialist

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Phone: 914-255-0000

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3. Regulatory Information

Table 1. Regulatory Information for ADVIA Centaur CMV IgM Assay

Trade Name	Atellica IM total PSA II (tPSAII)
Common Name	prostate-specific antigen (psa) for management of prostate cancers
Classification Name	tumor-associated antigen immunological test system
FDA Classification	Class 2
Review Panel	Immunology
Product Code	LTJ
Regulation Number	866.6010

4. Predicate Device Information

Predicate Device Name:

Siemens Atellica IM PSA assay, P950021/S015

The Atellica IM tPSAII assay is substantially equivalent to the Siemens Atellica IM PSA that was approved under P950021/S015, as shown below in the Substantial Equivalence Information section.

5. Intended Use / Indications for Use

Atellica® IM total PSA II (tPSAII) assay is for in vitro diagnostic use in the quantitative measurement of prostate-specific antigen (PSA) in human serum and plasma (EDTA and lithium-heparin) using the Atellica IM Analyzer.
This assay is indicated as an aid in the detection of prostate cancer in conjunction with a digital rectal exam (DRE) in men aged 50 years and older. Prostate biopsy is required for diagnosis of prostate cancer. This assay is further indicated as an aid in the management (monitoring) of patients with prostate cancer.
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6. Device Description

Material Description	Storage	Stability
tPSAII ReadyPack® primary reagent pack **Lite Reagent** 10.0 mL/reagent pack Unlabeled monoclonal mouse anti-fPSA antibody (~250 ng/mL); monoclonal mouse anti-PSA antibody (~180 ng/mL) labeled with acridinium ester; buffer; bovine serum albumin (BSA); preservative **Solid Phase** 20.0 mL/reagent pack Monoclonal mouse anti-PSA antibody (~3.5 µg/mL) labeled with biotin and bound to streptavidin paramagnetic particles; buffer; BSA; bovine gamma globulin (BGG); sodium azide (< 0.1%); preservative	Unopened at 2–8°C Onboard	Until expiration date on product 42 days
tPSAII CAL 2.0 mL/vial Purified PSA from human seminal fluid in buffer; BSA; NaN3 (< 0.1%)	Unopened at 2–8°C Opened at 2–8°C On the system at room temperature	Until expiration date on product 30 days 8 hours

Please note that tPSAII assay will have two configurations: 100 tests kit and 500 tests kit (5 x 100T in the carton)

7. Comparison of Technological Characteristics with the Predicate Device

	Candidate Device	**Predicate**
Item	**Atellica IM tPSAII**	**Atellica IM PSA**
Intended Use	The Atellica IM total PSA II (tPSAII) assay is for *in vitro* diagnostic use in the quantitative measurement of prostate-specific antigen (PSA) in human serum and plasma (EDTA and lithium heparin) using the Atellica IM Analyzer. This assay is indicated as an aid in the detection of prostate cancer in conjunction with a digital rectal exam (DRE) in men aged 50 years and older. Prostate biopsy is required for diagnosis of prostate cancer. This assay is further indicated as an aid in the management (monitoring) of patients with prostate cancer.	The Atellica IM Prostate-Specific Antigen (PSA) assay is for in vitro diagnostic use in the quantitative measurement of prostate-specific antigen (PSA) in human serum using the Atellica IM Analyzer. This assay is indicated for the measurement of serum PSA in conjunction with a digital rectal exam (DRE) as an aid in the detection of prostate cancer in men aged 50 years and older. This assay is further indicated as an aid in the management (monitoring) of patients with prostate cancer.
Instruments	Atellica IM	Same
Measurement	Quantitative	Same
Technology	Chemiluminescence	Same
Operating Principle	Sandwich immunoassay	Same
Sample type	Serum, Plasma	Serum
Sample Volume	30 uL	35 uL
Calibration	2 levels are included in each kit	Same
Detection Antibody	Unlabeled monoclonal mouse anti-free-PSA (fPSA) antibody (~250 ng/mL); monoclonal mouse anti-PSA antibody (~180 ng/mL) labeled with acridinium ester	Polyclonal goat anti-PSA antibody (~77 ng/mL) labeled with acridinium ester
Capture Antibody	Monoclonal mouse anti-PSA antibody (~3.5 µg/mL) labeled with biotin and bound to streptavidin paramagnetic particles	Monoclonal mouse anti-PSA antibody (~25 µg/mL) covalently coupled to paramagnetic particles
Measuring Interval	0.009 – 50.000 ng/mL	0.04–100.00 ng/mL

8. Performance Characteristics: Atellica IM tPSAII assay

Substantial equivalence was demonstrated by testing performance characteristics, listed below, including method comparison, imprecision, reproducibility, interfering and cross-reactive substances

8.1 Precision

Please refer to data provided in Atellica IM tPSAII assay PMA P240021

8.2 *Reproducibility*

Please refer to data provided in Atellica IM tPSAII assay PMA P240021

8.3 *Interference*

Please refer to data provided in Atellica IM tPSAII assay PMA P240021

8.4 *Cross-reactivity*

Please refer to data provided in Atellica IM tPSAII assay PMA P240021

8.5 *Matrix Comparison*

Please refer to data provided in Atellica IM tPSAII assay PMA P240021

8.6 *Traceability and Stability:*

Please refer to data provided in Atellica IM tPSAII assay PMA P240021

8.7 *Clinical Studies*

Studies were performed for the Atellica IM tPSAII assay to evaluate clinical performance in the intended use population - men diagnosed with prostate cancer (N=88). Samples to demonstrate clinical performance were prospectively collected per inclusion and exclusion criteria detailed in clinical protocol at several sites throughout the United States. Clinical performance testing was performed at one external testing site. Results from the testing were compared to the acceptance criteria.
In monitoring a population of patients with prostate cancer (N=88 subjects, across 323 timepoints), the Atellica IM hsPSA assay had equivalent performance to a comparative assay in terms of predicting disease status. The positive percent agreement between the two assays was 91.8% (45/49), with a 95% bootstrap confidence interval of 80.8%–96.8%, and the negative percent agreement between the two assays was 96.7% (265/274), with a 95% bootstrap confidence interval of 93.8%–98.3%. Results were established using the Atellica IM Analyzer. The data generated during this clinical study support the proposed intended use of the assay.

9. Proposed Labeling

The labeling satisfies the requirements of 21 CFR Part 809.10.

10. Conclusions

Based on the results of comparative testing, Atellica IM tPSAII assay is substantially equivalent in principle and performance to the currently marketed predicate device, Atellica IM PSA assay approved under P950021/S015.