



September 22, 2026

Alfa Scientific Designs, Inc.
% Jenny Xia
Director
LSI International, Inc.
504 E Diamond Ave.
Suite H
Gaithersburg, Maryland 20877

Re: K262299

Trade/Device Name: Instant-View® hCG Combo II Cassette Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: September 14, 2026
Received: September 14, 2026

Dear Jenny Xia:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JOSEPH A.
KOTAREK -S

Digitally signed by JOSEPH
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Date: 2026.09.22 10:02:14
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Joseph Kotarek, Ph.D.
Branch Chief
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

Indications for Use

510(k) Number (if known)

K262299

Device Name

Instant-View® hCG Combo II Cassette Test

Indications for Use (Describe)

The Instant-View® hCG Combo II Cassette Test is a chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum. It is for use as an aid in the early detection of pregnancy. This test is for health care professional use only and not for self-testing.

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
K262299

1. Date: September 1, 2026
2. Submitter: Alfa Scientific Designs Inc.
13200 Gregg Street
Poway, CA 92064
3. Contact person: Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org
4. Device Name: Instant-View® hCG Combo II Cassette Test

Classification: Class II

Product Code	CFR #	Panel
JHI	862.1155, Human chorionic gonadotropin (HCG) test system	Clinical Chemistry

5. Predicate Device:
K203272, Alltest Pregnancy Rapid Combo Test Cassette
6. Intended Use
The Instant-View® hCG Combo II Cassette Test is a chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum. It is for use as an aid in the early detection of pregnancy.
This test is for health care professional use only and not for self-testing.
7. Device Description
The Instant-View® hCG Combo II Cassette Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine or serum for the early detection of pregnancy. During pregnancy, HCG is produced by the placenta shortly after the embryo attaches to the uterine lining. The test device is used as a single cassette device.
8. Substantial Equivalence Information

A summary comparison of features of the Instant-View® hCG Combo II Cassette Test and the predicate device is provided in the following table.

Item	Device	Predicate K203272
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy.	Same
Specimen	Urine or serum	Same
Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Detection reagent	Colloidal gold	Same
Read time	Serum: 5 minutes Urine: 5 minutes	Serum: 5 minutes Urine: 3 minutes
Usage	For prescription use	Same
Cut-Off Values	10 mIU/mL for serum 20 mIU/mL for urine	Same
Configurations	Cassette	Same
Storage	2 – 30°C	Same

9. Test Principle

The test strip in the device consists of a conjugate pad containing a mouse monoclonal anti-hCG antibody conjugated to colloidal gold, and a nitrocellulose membrane precoated with a rabbit monoclonal anti-human CGA antibody at the test line (T line) and goat anti-mouse IgG at the control line (C line).

When an adequate amount of specimen is applied to the sample well of the device, hCG in the specimen binds to the anti-hCG antibody-gold conjugate in the conjugate pad, forming a complex that migrates along the membrane strip. If the hCG level is at or above 20 mIU/mL in urine or 10 mIU/mL in serum, the complex will bind to the capture antibody pre-coated on the T line, developing a colored band. If the specimen contains no hCG or if the hCG level below the detection limit, the T line will not develop. The goat anti-mouse antibody pre-coated on the C line will always bind to the gold-antibody conjugate, forms a colored line regardless of the presence or absence of hCG.

10. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility/Cut-Off Value

Negative serum or urine specimens were spiked with varying hCG (commercially available and traceable to the 6th WHO international Standard) concentrations. The spiked samples were measured in 6 replicates each day for 5 days using 3 different lots at three testing sites. Tests were performed by six different operators for each sample concentration. Results are shown in the following tables.

Serum

hCG Concentration (mIU/mL)	Site 1 Lot 3		Site 2 Lot 1		Site 3 Lot 2		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
2	30	0	30	0	30	0	90	0	100	0
5	30	0	30	0	30	0	90	0	100	0
7	4	26	3	27	4	26	11	79	12.2	87.8
8.5	3	27	2	28	2	28	7	83	7.8	92.2
10	0	30	0	30	0	30	0	90	0	100
12	0	30	0	30	0	30	0	90	0	100
15	0	30	0	30	0	30	0	90	0	100
25	0	30	0	30	0	30	0	90	0	100

Urine

hCG Concentration (mIU/mL)	Site 1 Lot 3		Site 2 Lot 1		Site 3 Lot 2		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
5	30	0	30	0	30	0	90	0	100	0
10	30	0	30	0	30	0	90	0	100	0
15	26	4	27	3	27	3	80	10	88.9	11.1
17.5	2	28	2	28	3	27	7	83	7.8	92.2
20	0	30	0	30	0	30	0	90	0	100
25	0	30	0	30	0	30	0	90	0	100
30	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100

Cut-off values of 10 mIU/mL for serum and 20 mIU/mL for urine are verified.

b. Stability

Stable at 2-30°C for 24 months based on the accelerated stability study at 60°C.

c. Specificity / Cross Reactivity

High Dose Effect

Negative urine (serum) samples were spiked with varying high hCG concentrations ranging from 500 to 2,000,000 mIU/mL. The spiked samples were tested by 3 different lots and 3 different operators. No hook effect was observed at these concentrations.

Effects of hCG β -core fragment

Negative and positive samples (5 and 10 mIU/mL hCG in serum; 10 and 20 mIU/mL hCG in urine) were spiked with various concentrations of β -core fragment hCG (0 to 2×10^6 pmol/L). These samples were tested by 3 different lots and 3 different operators. No difference was observed for different lots and different operators. No interference from β -core fragment was observed at concentrations up to 2,000,000 pmol/L for both serum and urine samples.

Effects of glycoprotein LH, FSH and TSH

Negative and positive samples (10 and 20 mIU/mL hCG for urine, and 5 and 10 mIU/mL hCG for serum) were spiked with various concentrations of other glycoprotein hormones such as LH, FSH, and TSH. Samples were tested using three different lots by three operators. No interference was observed for these samples for the device at LH concentrations up to 500 IU/mL, FSH concentrations up to 1000 mIU/mL, and TSH concentrations up to 1000 μ IU/mL.

d. Interference

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked in both hCG negative (5mIU/mL for serum, 10mIU/mL for urine) and hCG positive (10mIU/mL for serum, 20mIU/mL for urine) samples. Each sample was tested using 3 different lots of the testing kit. Results are shown in the following table.

Interferents	Concentration	Negative hCG			Positive hCG		
		Lot1	Lot2	Lot3	Lot1	Lot2	Lot3
Acetaminophen	20 mg/dl	-	-	-	+	+	+
Acetoacetic Acid	2000 mg/dl	-	-	-	+	+	+
Ascorbic Acid	20 mg/dl	-	-	-	+	+	+
Atropine	20 mg/dl	-	-	-	+	+	+
Acetosalicic Acid	20 mg/dl	-	-	-	+	+	+
Albumin	2000mg/dl	-	-	-	+	+	+
Bilirubin (urine)	2 mg/dl	-	-	-	+	+	+
Bilirubin (serum)	40 mg/dl	-	-	-	+	+	+
Caffeine	20 mg/dl	-	-	-	+	+	+
Codeine	10 mg/dl	-	-	-	+	+	+
Ephedrine	20 mg/dl	-	-	-	+	+	+
EDTA	80 mg/dl	-	-	-	+	+	+
Ethanol	1%	-	-	-	+	+	+

Gentisic Acid	20 mg/dl	-	-	-	+	+	+
Glucose	2000 mg/dl	-	-	-	+	+	+
Hemoglobin	2000 mg/dl	-	-	-	+	+	+
Methadone	10 mg/dl	-	-	-	+	+	+
Phenylpropanolamine	20 mg/dl	-	-	-	+	+	+
Phenothiazine	20 mg/dl	-	-	-	+	+	+
Pregnanediol	1.5 mg/dl	-	-	-	+	+	+
Salicylic Acid	20 mg/dl	-	-	-	+	+	+
B-hydroxybutyrate	2000 mg/dL	-	-	-	+	+	+
Benzoylcegonine	10 mg/dL	-	-	-	+	+	+
Cannabinol	10 mg/dL	-	-	-	+	+	+
Methanol	10%	-	-	-	+	+	+
Estriol-17-beta	1.4 mg/dL	-	-	-	+	+	+
Thiophene	20 mg/dl	-	-	-	+	+	+
Ampicillin	20 mg/dl	-	-	-	+	+	+
Tetracycline	20 mg/dl	-	-	-	+	+	+
Ketone	20 mg/dl	-	-	-	+	+	+
Total cholesterol (serum only)	250 mg/dl	-	-	-	+	+	+
Triglycerides (serum only)	1200 mg/dl	-	-	-	+	+	+
High-density lipoprotein (serum only)	70 mg/dl	-	-	-	+	+	+

All data shows that there is no interference for the listed compounds at the stated concentrations.

e. Effect of Urine Specified Gravity and Urine pH

Negative and positive urine samples containing 10 and 20 mIU/mL hCG were tested at pH values from 4 to 9 or at density values ranging from 1.000 to 1.035 using 3 different lots by 3 different operators. Data show that there is no interference from pH ranging from 4 to 9 and specific gravity ranging from 1.000 to 1.035 of tested urine samples.

2. Comparison Studies

A method comparison study was performed, comparing the results obtained from the the Instant-View® hCG Combo II Cassette Test to the results from predicate devices (K203272). 126 urine and 124 serum samples were collected from 250 women (about 40% of them were pregnant, early stage at less than 5 weeks) from three testing sites. Samples were randomly collected at various times throughout the day. Ages ranged from 18 to 49 years. Samples were tested by different health professionals with the

proposed and the predicate devices at each site. The obtained results are shown in the following tables.

Summary Results for Urine

New Device	Cleared device	+	-
	+	49	0
	-	0	77

Summary Results for Serum

New Device	Cleared device	+	-
	+	54	0
	-	0	70

The study results show 100% agreement for all samples.

3. Clinical Studies

Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, the Instant-View® hCG Combo II Cassette Test is substantially equivalent to the predicate.