January 31, 2025

Nanjing Synthgene Medical Technology Co., Ltd.
Alvin Qian
Registration Manager
Building B6-2, No. 9, Weidi Road, Xianlin University Town
Xianlin Subdistrict, Qixia District
Nanjing, Jiangsu 210000
China

Re: K242135
Trade/Device Name: Synthgene Home Test HCG Test Strip; Synthgene Home Test HCG Test Cassette; Synthgene Home Test HCG Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: December 20, 2024
Received: December 20, 2024

Dear Alvin Qian:

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,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2025.01.31 08:35:49 -05'00'

Joseph Kotarek, Phd.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

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.

Submission Number *(if known)*

k242135

Device Name

Synthgene Home Test HCG Test Strip;
Synthgene Home Test HCG Test Cassette;
Synthgene Home Test HCG Test Midstream

Indications for Use *(Describe)*

Synthgene Home Test HCG Test Midstream is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Synthgene Home Test HCG Test Cassette is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Synthgene Home Test HCG Test Strip is used for the qualitative detection of human chorionic gonadotropin in urine to 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.

510(k) summary

K242135

1. Date Prepared

January 24, 2025

2. Submitter

Company Name: Nanjing Synthgene Medical Technology Co., Ltd.

Address: Building B6-2, No. 9, Weidi Road, Xianlin University Town, Xianlin Subdistrict, Qixia District, Nanjing City, Nanjing, Jiangsu, 210000, CHINA

Establishment Registration Number: 3016902172

Contact Person: ALVIN QIAN

Position: Registration Manager

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3. Proposed Device

Trade Name of Device: Synthgene Home Test HCG Test Strip

Synthgene Home Test HCG Test Cassette

Synthgene Home Test HCG Test Midstream

Classification Name: Kit, Test, Pregnancy, Hcg, Over The Counter

Classification: II

Product Code: LCX

Regulation Number: 21 CFR 862.1155

Review Panel: Clinical Chemistry

4. Predicate Devices

510(k) Number: K192123

Trade/Product Name: HIGHTOP Pregnancy Rapid Test Cassette

510(k) summary
HIGHTOP Pregnancy Rapid Test Strip

HIGHTOP Pregnancy Rapid Test Midstream

Regulation Name: Human chorionic gonadotropin (HCG) test system

Classification name: kit, test, pregnancy, hcg, over the counter

Regulation Number: 21 CFR 862.1155

Device Class: Class II

Product Code: LCX

Manufacturer: Qingdao Hightop Biotech Co., Ltd.

5. Device description

Synthgene Home Test HCG Test is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test devices are in three different formats: Strip, Cassette and Midstream. Each test kit contains the individually packaged test pen/strip/cassette, medical waste bag, urine cup and instructions for Use. The cassette format also contains a dropper. The device is in a ready-to-use format and does not require assembly before use.

6. Indication for use

Synthgene Home Test HCG Test Midstream is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Synthgene Home Test HCG Test Cassette is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

Synthgene Home Test HCG Test Strip is used for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

7. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the candidate device and the predicate devices are listed in table below.

Table 1 Comparison of Candidate Devices with the Predicate Devices

Similarities		
Item	**Candidate device**	**Predicate device (K192123)**
Product name	Synthgene Home Test HCG Test Strip Synthgene Home Test HCG Test Cassette Synthgene Home Test HCG Test Midstream	HIGHTOP Pregnancy Rapid Test Cassette HIGHTOP Pregnancy Rapid Test Strip HIGHTOP Pregnancy Rapid Test Midstream
Intended Use	Early detection of pregnancy.	Same
Specimen Type	Urine	Same
Assay methodology	Immunochromatographic assay	Same
Sensitivity	25 mIU/mL	Same
Results	Qualitative	Same
Intended user	Over the counter use	Same
Device format	Strip/Cassette/Midstream	Same
Differences		
Reading Time	5-20 minutes	5 minutes

8. Test Principle

The product adopts the principle of double antibody sandwich. When human chorionic gonadotropin is present in the sample, the HCG antigen in the sample reacts with the colloidal gold-labeled antibody (HCG mAb1) on the conjugate pad to form the labeled antibody-antigen complex. The complex is chromatographed upward by capillary action and captured by the detection line (T line) antibody (HCG mAb2) coated on the nitrocellulose membrane, appearing as a red band. The complex continues to move chromatographically upward, and is captured by the control line (C line) antibody (goat anti-mouse IgG polyclonal antibody) coated on the nitrocellulose membrane, and a red band appears. When the concentration of HCG in the sample is lower than the sensitivity, the detection line (T line) does not develop color.

9. Performance Characteristics

9.1 Analytical performance

a Precision/Reproducibility/Sensitivity

Negative urine collected from females was spiked with hCG standard to hCG concentrations of 0, 12.5, 18.75, 22.5, 25, 50, 100 and 200 mIU/mL. The spiked samples were measured using 3 different lots for each format. Tests were performed by three different operators for each sample concentration in 10 runs per day per lot for 5 days. For each format of the device, a total of 450 replicates were tested for each HCG concentration. Based on the test results, the sensitivity of Synthgene Home Test HCG Test is demonstrated to be 25 mIU/mL. There were no significant differences in performance between lots, between operators, between sites, between time of day and between days. The results are summarized in the table below:

Midstream Format

Dip method

Sample No.	HCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total results		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	20	130	20	130	17	133	57	393	87.3%	12.7%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

Midstream method

Sample No.	HCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total results		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	23	127	24	126	21	129	68	382	84.9%	15.1%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

Cassette Format

Sample No.	HCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total results		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	19	131	24	126	19	131	62	388	86.2%	13.8%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

Strip Format

Sample No.	HCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total results		Pos	Neg
		-	+	-	+	-	+	-	+		
S1	0	150	0	150	0	150	0	450	0	0%	100%
S2	12.5	150	0	150	0	150	0	450	0	0%	100%
S3	18.75	150	0	150	0	150	0	450	0	0%	100%
S4	22.5	23	127	23	127	21	129	67	383	85.11%	14.89%
S5	25	0	150	0	150	0	150	0	450	100%	0%
S6	50	0	150	0	150	0	150	0	450	100%	0%
S7	100	0	150	0	150	0	150	0	450	100%	0%
S8	200	0	150	0	150	0	150	0	450	100%	0%

b Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

Traceability, Stability, Expected values (controls, calibrators, or methods) Synthgene Home Test HCG Test is calibrated against reference material traceable to WHO International Standard 6th edition (NIBSC code:18/244).

A shelf-life stability test of the devices was performed by Real-time Stability Study. The results showed that the devices were stable for 24 months when stored at 2~30℃ in the sealed foil pouch.

c Cross reactivity

To evaluate specificity and cross-reactivity, negative and positive urine samples (0

mIU/mL and 25 mIU/mL) were spiked with various concentrations of glycoprotein hormones LH, FSH, TSH and hCG β-core fragment. The results showed that there is no interference at 500 mIU/mL LH, 1000 mIU/mL FSH, 1000 mIU/L TSH and 2,000,000 pmol/L hCG β-core fragment for both negative and positive urine samples.

d Interfering substance

A study was performed to evaluate the potential for interference by certain exogenous and endogenous compounds. Each substance was prepared by diluting stock interference material to the desired concentration. Urine specimens containing 0 and 25 mIU/ml HCG were spiked with the potential interferents to obtain the desired test concentration. The results show that no interferences were observed from substance at the following concentrations for both negative and positive urine samples.

Interfering substance	Substances concentration
Acetaminophen	0.2 mg/mL
Aspirin	0.2 mg/mL
Vitamin C	0.2 mg/mL
Atropine	0.2 mg/mL
Ampicillin	0.2 mg/mL
Tetracycline	0.2 mg/mL
2,5-Dihydroxybenzoic acid	0.2 mg/mL
Caffeine	0.2 mg/mL
Phenothiazine	0.2 mg/mL
Ethanol	1%
Human Albumin	20 mg/mL
Triglyceride	8 mg/mL
Hemoglobin	5 mg/mL
Bilirubin	0.02 mg/mL
Glucose	20 mg/mL
Acetoacetic Acid	20 mg/mL
Asorbic Acid	0.2 mg/mL
B-hydroxybutyrate	20 mg/mL
Ephedrine	0.2 mg/mL
Gentisic Acid	0.2 mg/mL
Phenylpropanolamine	0.2 mg/mL
Salicylic Acid	0.2 mg/mL
EDTA	0.8 mg/mL
Benzoylecgonine	0.1 mg/mL
Cannabinol	0.1 mg/mL
Codeine	0.06 µg/mL
Methanol	10%
Estriol-17-beta	14 mg/mL
Pregnanediol	15 µg/mL
Thiophene	0.2 mg/mL
Ketone	0.2 mg/mL

e Effects of Urine pH

To evaluate potential interference from changes in pH, urine samples containing 0 mIU/mL and 25 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that changes in pH range of 4 - 9 do not interfere in the results that were either positive or negative for hCG.

f Effects of Specific Gravity

To evaluate potential interference from changes in specific gravity, urine samples containing 0 mIU/mL and 25 mIU/mL hCG were tested at specific gravity values at 1.000, 1.002, 1.009, 1.012, 1.018, 1.028, 1.032 and 1.035. The results demonstrated that urine samples with a specific gravity between 1.000-1.035 do not interfere in the results that were either positive or negative for hCG.

g Hook effect test

Negative urine samples were spiked with varying hCG concentrations (2325, 4650, 9300, 11,625, 58,125, 116,250, 232,500, 465,000, 930,000 and 1,860,000 mIU/mL). All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentrations ranging from 2325 to 1,860,000 mIU/ml.

9.2 Method comparison study

a Method comparison with predicate device

Urine samples were collected from 333 women aged 18 – 49 who presented for pregnancy testing at 3 sites. Samples were randomly collected at various times throughout the day and blinded before being tested by professionals using the candidate devices and the predicate device. A total of 121 samples tested with the Synthgene Home Test HCG Test Midstream, 109 samples tested with the Synthgene Home Test HCG Test Cassette, and 103 samples tested with the Synthgene Home Test HCG Test Strip. Of the 121 samples tested using the midstream format, 61 were tested in dip sampling mode and 60 were tested in midstream sampling mode. The results of the study are summarized in the tables below:

Midstream Format - Dip application method：

Synthgene Home Test	HIGHTOP Pregnancy Rapid Test Midstream	Total

HCG Test Midstream	Positive	Negative	
Positive	38	0	38
Negative	0	23	23
Total	38	23	61

Midstream Format - Midstream application method：

Synthgene Home Test HCG Test Midstream	HIGHTOP Pregnancy Rapid Test Midstream		Total
	Positive	Negative	
Positive	40	0	40
Negative	0	20	20
Total	40	20	60

For Synthgene Home Test HCG Test Cassette

Synthgene Home Test HCG Test Cassette	HIGHTOP Pregnancy Rapid Test Cassette		Total
	Positive	Negative	
Positive	60	0	60
Negative	0	49	49
Total	60	49	109

For Synthgene Home Test HCG Test Strip

Synthgene Home Test HCG Test Strip	HIGHTOP Pregnancy Rapid Test Strip		Total
	Positive	Negative	
Positive	54	0	54
Negative	0	49	49
Total	54	49	103

b Matrix comparison

Not applicable. The device is for use with urine samples only.

9.3 Clinical studies

a Clinical Sensitivity

Not applicable.

b Clinical specificity

Not applicable.

c Other clinical supportive data (when a. and b. are not applicable):

Lay-User Study

A lay user study was conducted at three sites with female subjects who were able to adequately understand and use the instructions for use to conduct testing. These subjects had diverse educational and professional backgrounds and their age range was between 18 and 49 years old. A total of 333 subjects participated in the study, included 121 lay-users using the Synthgene Home Test HCG Test Midstream, 109 lay-users using the Synthgene Home Test HCG Test Cassette, and 103 lay-users using the Synthgene Home Test HCG Test Strip.

The test results are summarized below:

Midstream Format - Dip application method

Synthgene Home Test HCG Test Midstream	HIGHTOP Pregnancy Rapid Test Midstream		Total
	Positive	Negative	
Positive	38	0	38
Negative	0	23	23
Total	38	23	61

Midstream Format - Midstream application method:

Synthgene Home Test HCG Test Midstream	HIGHTOP Pregnancy Rapid Test Midstream		Total
	Positive	Negative	
Positive	40	0	40
Negative	0	20	20
Total	40	20	60

For Synthgene Home Test HCG Test Cassette

Synthgene Home Test HCG Test Cassette	HIGHTOP Pregnancy Rapid Test Cassette		Total
	Positive	Negative	
Positive	60	0	60
Negative	0	49	49
Total	60	49	109

For Synthgene Home Test HCG Test Strip

Synthgene Home Test HCG Test Strip	HIGHTOP Pregnancy Rapid Test Strip		Total
	Positive	Negative	

Positive	54	0	54
Negative	0	49	49
Total	54	49	103

Each lay user was given a questionnaire to assess the readability of the labeling. The results of the questionnaire reflected that the consumers found the test easy to use and that they did not have trouble understanding the labeling and interpreting the results.

d Clinical cut-off:

Not applicable

e Expected values/Reference range:

Not applicable.

10. Conclusion

Based on the test principle and acceptable performance characteristics including precision, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the Synthgene Home Test HCG Test Strip, Synthgene Home Test HCG Test Cassette, and Synthgene Home Test HCG Test Midstream are substantially equivalent to the predicate.