February 5, 2024

Assure Tech (Hangzhou) Co., Ltd.
% Joe Shia
Director
LSI International
504 E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K233174
Trade/Device Name: FaStep™ Pregnancy Rapid Test Strip; FaStep™ Pregnancy Rapid 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 19, 2023
Received: December 19, 2023

Dear Joe Shia:

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.

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.
Acting Division 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233174

Device Name
FaStep™ Pregnancy Rapid Test Strip
FaStep™ Pregnancy Rapid Test Midstream

Indications for Use *(Describe)*

The FaStep™ Pregnancy Rapid Test Strip is a rapid, visual immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The test is an in-vitro diagnostic strip intended for use as an aid in the early detection of pregnancy. The FaStep™ Pregnancy Rapid Test Strip is designed for self-testing use.

The FaStep™ Pregnancy Rapid Test Midstream is a rapid, visual immunoassay for the qualitative detection of human chorionic gonadotropin(hCG) in urine. The test is an in-vitro diagnostic device intended for use as an aid in the early detection of pregnancy. The FaStep™ Pregnancy Rapid Test Midstream is designed for self-testing use.

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

K233174

1. Date: February 5, 2024

2. Submitter:
Assure Tech. (Hangzhou) Co., Ltd.
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China

3. Contact person:
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4. Device Name: FaStep™ Pregnancy Rapid Test Strip
FaStep™ Pregnancy Rapid Test Midstream
Classification: Class II
Product Code: LCX
CFR: 862.1155

5. Predicate Devices: Fastep™ At-Home Pregnancy Test (K122907)

6. Intended Use

The FaStep™ Pregnancy Rapid Test Strip is a rapid, visual immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The test is an in-vitro diagnostic strip intended for use as an aid in the early detection of pregnancy. The FaStep™ Pregnancy Rapid Test Strip is designed for self-testing use.

The FaStep™ Pregnancy Rapid Test Midstream is a rapid, visual immunoassay for the qualitative detection of human chorionic gonadotropin(hCG) in urine. The test is an in-vitro diagnostic device intended for use as an aid in the early detection of pregnancy. The FaStep™ Pregnancy Rapid Test Midstream is designed for self-testing use.

7. Device Description

FaStep™ Pregnancy Rapid Test Strip is sold as a strip format and FaStep™

Pregnancy Rapid Test Midstream is sold as a midstream format. FaStep™ Pregnancy Rapid Test Midstream consists of a single test strip assembled in a plastic housing, with an absorbent tip, and is designed to be tested in dip or midstream mode. FaStep™ Pregnancy Rapid Test Strip is a single test strip. FaStep™ Pregnancy Rapid Test Midstream contains one test sealed in a desiccated aluminum pouch and Instructions for Use. FaStep™ Pregnancy Rapid Test Strip contains one test strip sealed in a desiccated aluminum pouch and Instructions for Use. The device is in a ready-to-use format and does not require assembly before use.

8. Substantial Equivalence Information

Similarities		
Item	Candidate device	Predicate device
Intended use	Early detection of pregnancy	Early detection of pregnancy
Specimen	Urine	Urine
Assay technical	Immunochromatographic assay	Immunochromatographic assay
Sensitivity	20 mIU/mL	20 mIU/mL
Results	Qualitative	Qualitative
Read time	3-10 minutes	3-5 minutes
Device format	Midstream, Strip	Midstream
Target user	Over the counter use	For over-the-counter

9. Test Principle

FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream use lateral flow immunoassay for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. If hCG is present in the sample, it will reach the Test Zone ("T") of the membrane and form a colored line. When the test is performed properly, a colored line will always appear in the Control Zone ("C"). The test result is shown on the strip (for the strip version) or in the result window (for the midstream version) and read visually between 3 and 10 minutes of urine application. Two distinct colored lines, one in the Test Zone and another in the Control Zone indicate a positive test result (pregnant). Absence of a colored line in the Test Zone and only a colored line in the Control Zone indicates a negative test result (not pregnant). Absence of a colored line in the Control Zone even in the presence of a colored line in the Test Zone indicates an invalid test result.

10. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility/Sensitivity

Negative female urine was spiked with hCG standard (Traceable to the 5th WHO) to hCG concentrations of 0, 10, 12.5, 15, 17.5, 20, 50, 100 and 200 mIU/mL. Each sample was tested in 10 replicates per day for 5 days for each device lot. Total of three device lots for each format were tested. Tests were performed by three different operators for each sample concentration.
The results are summarized in the table below:

FaStep™ Pregnancy Rapid Test Midstream (in-stream method)

hCG Concentration (mIU/mL)	Operator 1		Operator 2		Operator 3		Total result		% Negative	% Positive
	Lot 1		Lot 2		Lot 3					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
10	50	0	50	0	50	0	150	0	100%	0%
12.5	46	4	45	5	43	7	134	16	89.3%	10.7%
15	22	28	27	23	25	25	74	76	49.3%	50.7%
17.5	6	44	6	44	5	45	17	133	11.3%	88.7%
20	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%
100	0	50	0	50	0	50	0	150	0%	100%
200	0	50	0	50	0	50	0	150	0%	100%

FaStep™ Pregnancy Rapid Test Midstream format (dip method)

hCG Concentration (mIU/mL)	Operator 1		Operator 2		Operator 3		Total result		% Negative	% Positive
	Lot 1		Lot 2		Lot 3					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
10	50	0	50	0	50	0	150	0	100%	0%
12.5	44	6	44	6	46	4	134	16	89.3%	10.7%
15	24	26	26	24	27	23	77	73	51.3%	48.7%
17.5	7	43	5	45	4	46	16	134	10.7%	89.3%
20	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%
100	0	50	0	50	0	50	0	150	0%	100%
200	0	50	0	50	0	50	0	150	0%	100%

FaStep™ Pregnancy Rapid Test Strip

hCG Concentration	Operator 1	Operator 2	Operator 3	Total result	% Negative	% Positive

(mIU/mL)	Lot 1		Lot 2		Lot 3					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
10	50	0	50	0	50	0	150	0	100%	0%
12.5	45	5	45	5	44	6	134	16	89.3%	10.7%
15	23	27	26	24	24	26	73	77	48.7%	51.3%
17.5	7	43	5	45	6	44	18	132	12.0%	88.0%
20	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%
100	0	50	0	50	0	50	0	150	0%	100%
200	0	50	0	50	0	50	0	150	0%	100%

FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream exhibited reproducibility of results.
Based on the above results, the sensitivity of FaStep™ Pregnancy Rapid Test is demonstrated to be 20 mIU/mL.

b. Linearity/assay reportable range:
Linearity is not applicable since this is a qualitative test.

Hook effect test:
Negative urine samples were spiked with varying hCG concentrations (6,250 mIU/mL, 12,500 mIU/mL, 25,000 mIU/mL, 50,000 mIU/mL, 100,000 mIU/mL, 200,000 mIU/mL and 500,000 mIU/mL). All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Traceability:
FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream are calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

Stability:
A 27-month real time stability test was carried out to verify the shelf-life stability of the device. Three batches for each format in sealed foil pouch are stable for 30 months at 2°C and 30°C, and the shelf-life is claimed to be 24 months.

d. Specificity and cross reactivity
To evaluate specificity, 300 urine samples were collected from normal, non-pregnant female in pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old) and post-menopausal (>55 years old) groups. 100 people for each age group. In each age group, 50 participants were tested with test midstream

using dip method, and 50 participants tested with test midstream using in-stream method. No false positive results were observed for any of the age groups.

To evaluate cross-reactivity, negative and positive urine samples (0, 10 and 20 mIU/mL hCG) were spiked with potential cross reactants (500 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 μIU/mL hTSH). No cross-reactivity was observed at tested concentration.
To evaluate the effect of the hCG β-core fragment, Negative urine samples (0 and 10 mIU/mL hCG) and positive urine samples (20 and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment (hCGβcf) at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000pmol/L and 500,000pmol/L. The performance of FaStep™ Pregnancy Rapid Test is not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

e. Interfering substance

To evaluate potential interference with FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream, urine samples containing 0, 10 and 20 mIU/mL hCG were spiked with the interfering substance to obtain the certain desired test concentration. No interference effect was observed at the tested concentration shown in table below:

Substance	***Concentration***
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dl
Albumin	2000 mg/dL
Amoxicillin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Aspirin	80 mg/dL
Atropine	20 mg/dL
Benzoylecgonine	10 mg/dL
Bilirubin	40 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1%
Folic acid	0.03 mg/dL
Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	1000 mg/dL
Ibuprofen	40 mg/dL
Ketone	20 mg/dL

Methanol	1%
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic Acid	20 mg/dL
Tetracycline	20 mg/dL
Thiophene	20 mg/dL
Uric acid	23.5 mg/dL
Vitamin B1	80 mg/dL
β-hydroxybutyrate	2000 mg/dL

To evaluate the effect of urine pH on the results of FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream, urine samples containing 0, 10 and 20 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that urine pH ranges between 4 and 9 does not affect the performance of FaStep™ Pregnancy Rapid Test.

To evaluate the effect of urine density on the results of FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream, urine samples containing 0, 10 and 20 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.011, 1.015, 1.019, 1.024, 1.029 and 1.035. The results indicated that urine with a relative density of 1.000 to 1.035 does not affect the performance of FaStep™ Pregnancy Rapid Test.

B. Method comparison study

Method comparison with predicate device

The performance of the FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream was compared to the predicate test. Urine samples were collected from 267 women presenting to test for pregnancy. Total of the 139 women were pregnant and they were all in the early stage of less than 5 weeks. All samples were tested with candidate and predicate devices at three POC sites.

The results are summarized in the table below.

Candidate device		Predicate device		
		Positive	Negative	Total
FaStep™ Pregnancy Rapid Test Strip	Positive	74	0	74
	Negative	0	66	66
	Total	74	66	140

Candidate device		Predicate device		
		Positive	Negative	Total
FaStep™ Pregnancy Rapid Test Midstream (in-stream method)	Positive	65	0	65
	Negative	0	62	62

	Total	65	62	127

Candidate device		Predicate device		
		Positive	Negative	Total
FaStep™ Pregnancy Rapid Test Midstream (dip method)	Positive	65	0	65
	Negative	0	62	62
	Total	65	62	127

The conformity between FaStep™ Pregnancy Rapid Test Strip, FaStep™ Pregnancy Rapid Test Midstream and the predicate device is 100%.

C. Lay person study

267 women's individual pregnancy status was self-tested. Individuals with varying educational and occupational backgrounds from three sites were chosen for the study. Each subject tested her own urine sample using the device according to the package insert and provided a sample for professional testing.
The results are summarized in the table below.

A total of 140 subjects tested their urine samples using the FaStep™ Pregnancy Rapid Strip

FaStep™ Pregnancy Rapid Test Strip		Professional		
		Positive	Negative	Total
Layperson	Positive	74	0	74
	Negative	0	66	66
	Total	74	66	140

A total of 127 lay users tested their urine samples using the FaStep™ Pregnancy Rapid Midstream.

FaStep™ Pregnancy Rapid Test Midstream (instream and dip method)		Professional Result		Total
		Positive (+)	Negative (-)	
Lay User Result	Positive (+)	65	0	65
	Negative (-)	0	62	62
Total		65	62	127

From the above tables, the lay person results showed 100% positive and 100% negative conformity with the professional results.

Each lay person 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.

11. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that FaStep™ Pregnancy Rapid Test Strip and FaStep™ Pregnancy Rapid Test Midstream are substantially equivalent to the predicate.