December 20, 2024

Andon Health Co., Ltd.
Liu Yi
Official Correspondent
No 3, Jinping Street, Ya An Road, Nankai District
Tianjin, China

Re: K241394
Trade/Device Name: iHealth® Early Pregnancy Test; iHealth® Early Pregnancy Test Strip
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: November 15, 2024
Received: November 15, 2024

Dear Liu Yi:

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: 2024.12.20 12:59:38 -05'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistry and
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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)*
K241394

Device Name
iHealth® Early Pregnancy Test
iHealth® Early Pregnancy Test Strip

Indications for Use *(Describe)*

The iHealth® Early Pregnancy Test is an OTC in vitro diagnostic test used to assess early pregnancy by detecting the presence of the hCG (human chorionic gonadotropin) hormone in urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e., as early as five (5) days before the day of the expected period.

The iHealth® Early Pregnancy Test Strip is an OTC in vitro diagnostic test used to assess early pregnancy by detecting the presence of the hCG (human chorionic gonadotropin) hormone in urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e., as early as five (5) days before the day of the expected period.

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

1. Submitter's Information

Name:	Andon Health Co., Ltd.
Address:	No 3, Jinping Street, Ya An Road, Nankai District, Tianjin, P.R. China Tianjin China
Phone Number:	86-22-87611660
Contact:	Mr. Liu Yi
Email:	fda@jiuan.com

2. Device Information

Trade Name:	iHealth® Early Pregnancy Test iHealth® Early Pregnancy Test Strip
Model:	IHC-3000
Common Name:	Human chorionic gonadotropin (HCG) test system
510(k) Number	K241394
Device class:	Class II
Classification Name:	Kit, Test, Pregnancy, Hcg, Over The Counter
Regulation Number:	21 CFR 862.1155
Product Code(s):	LCX
Panel:	Clinical Chemistry (75)

3. Predicate Device

Manufacturer:	SPD Swiss Precision Diagnostics GmbH
Device Name:	Clearblue® Early Pregnancy Test
510(k) Number:	K213379
Classification	II
Product Code：	LCX

4. Device Description

The iHealth® Early Pregnancy Test is a lateral flow immunoassay technique device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine samples, and is indicated for use as an aid in early detection of pregnancy. The iHealth® Early Pregnancy Test is designed to detect as early as six (6) days before the day of the missed period, i.e., as early as five (5) days before the day of the expected period. Test result is displayed to the user as two lines for a 'Pregnant' result and one line for a 'Not Pregnant' result.

The iHealth® Early Pregnancy Test are in two different formats: Stick and Strip format. Two test formats use identical strips and each test strip in the device consists of: Sample pad, colloidal gold binding pad, nitrocellulose membrane, absorbent paper and PVC board, colloidal gold binding pad coated with hCG monoclonal antibody 1, test line(T Line) coated with hCG-monoclonal antibody 2 and control line(C Line) coated with goat anti-mouse IgG antibody.

Two formats have the same performance specifications. The difference is that Stick format is designed to be tested in dip or midstream method, and Strip format is tested in dip method only.

5. Intended Use

The iHealth® Early Pregnancy Test is an OTC in vitro diagnostic test used to assess early pregnancy by detecting the presence of the hCG (human chorionic gonadotropin) hormone in urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e., as early as five (5) days before the day of the expected period.

The iHealth® Early Pregnancy Test Strip is an OTC in vitro diagnostic test used to assess early pregnancy by detecting the presence of the hCG (human chorionic gonadotropin) hormone in urine. The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e., as early as five (5) days before the day of the expected period.

6. Comparison to Predicate Device

The following table is the comparison summary of the proposed subject device and predicate device.

Item	**Subject Device**	**Predicate Device (K213379)**
	iHealth® Early Pregnancy Test	**Clearblue® Early Pregnancy Test**

	iHealth® Early Pregnancy Test Strip	
Similarities		
Intended Use	Qualitative detection of human hCG for an aid in early detection of pregnancy.	Same
'Early Test' Claim	The test device is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period.	Same
Target User	Over-The-Counter use	Same
Sample Matrix	Urine	Same
Analyte	hCG	Same
Read Time	3-5 minutes	Same
hCG Sensitivity	10mIU/mL	Same
Test Principle	Lateral flow sandwich immune chromatographic assay with visual result display	Same
Assay Mobile Phase	Gold conjugate	Same
Control Mechanism	Visual	Same
Results Display	Visual Parallel Line 2 Lines = Pregnant 1 Line = Not Pregnant	Same
Test Type	Qualitative	Same
Differences		
Device Format	Two formats: Strip and Stick	One format
Sample application	Strip format: dip Stick format: midstream and dip	In-stream and dip
Traceability	WHO 5th International Standard for hCG	WHO 4th International Standard for hCG
Analyte Detection	Recognizes intact hCG and hCG β-subunit	Detects intact hCG. Scavenger system to remove intact hCG in the presence of

		FSH.

7. Performance characteristics

A. Analytical performance

a. Precision/Sensitivity

Not-pregnant female urine was spiked with hCG traceable to the 5th WHO international standard with hCG concentrations of 0, 3, 5, 7.5, 10, 12.5, 15 and 25mIU/mL. Each standard was tested with devices from three different lots for each format. The study was performed by nine operators over five days at three sites.

The results are summarized in the tables below:

iHealth® Early Pregnancy Test Strip format:

hCG concentration（mIU/mL）	Lot 1			Lot 2			Lot 3			**Total result**		
	Negative (n)	Positive (n)	Positive (%)	Negative (n)	Positive (n)	Positive (%)	Negative (n)	Positive (n)	Positive (%)	**Negative (n)**	**Positive (n)**	**Positive (%)**
0	135	0	0	135	0	0	135	0	0	405	0	0
3	135	0	0	135	0	0	135	0	0	405	0	0
5	58	77	57.0%	53	82	60.7%	59	76	56.3%	170	235	58.0%
7.5	41	94	69.6%	43	92	68.1%	35	100	74.1%	119	286	70.6%
10	0	135	100%	0	135	100%	0	135	100%	0	405	100%
12.5	0	135	100%	0	135	100%	0	135	100%	0	405	100%
15	0	135	100%	0	135	100%	0	135	100%	0	405	100%
25	0	135	100%	0	135	100%	0	135	100%	0	405	100%

iHealth® Early Pregnancy Test Stick format (dip method)

hCG concentration（mIU/mL）	Lot 1			Lot 2			Lot 3			**Total result**		
	Negative (n)	Positive (n)	Positive (%)	Negative (n)	Positive (n)	Positive (%)	Negative (n)	Positive (n)	Positive (%)	**Negative (n)**	**Positive (n)**	**Positive (%)**
0	135	0	0	135	0	0	135	0	0	405	0	0
3	135	0	0	135	0	0	135	0	0	405	0	0

5	62	73	54.1%	58	77	57.0%	68	67	49.6%	188	217	53.6%
7.5	48	87	64.4%	37	98	72.6%	43	92	68.1%	128	277	68.4%
10	0	135	100%	0	135	100%	0	135	100%	0	405	100%
12.5	0	135	100%	0	135	100%	0	135	100%	0	405	100%
15	0	135	100%	0	135	100%	0	135	100%	0	405	100%
25	0	135	100%	0	135	100%	0	135	100%	0	405	100%

iHealth® Early Pregnancy Test Stick format (midstream method)

hCG concentration（mIU/mL）	Lot 1			Lot 2			Lot 3			**Total result**		
	Negative (n)	Positive (n)	Positive (%)	Negative (n)	Positive (n)	Positive (%)	Negative (n)	Positive (n)	Positive (%)	**Negative (n)**	**Positive (n)**	**Positive (%)**
0	135	0	0	135	0	0	135	0	0	405	0	0
3	135	0	0	135	0	0	135	0	0	405	0	0
5	67	68	50.4%	63	72	53.3%	66	69	51.1%	196	209	51.6%
7.5	44	91	67.4%	48	87	64.6%	49	86	63.7%	141	264	65.2%
10	0	135	100%	0	135	100%	0	135	100%	0	405	100%
12.5	0	135	100%	0	135	100%	0	135	100%	0	405	100%
15	0	135	100%	0	135	100%	0	135	100%	0	405	100%
25	0	135	100%	0	135	100%	0	135	100%	0	405	100%

Based on the above results, the sensitivity of iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip is demonstrated to be 10 mIU/mL.

b. Linearity/Assay measuring range

N/A. This is a qualitative detection device.

c. Hook effect test

Not-pregnant female urine was spiked with hCG to concentrations of 0 mIU/mL, 10mIU/mL, 1,000 mIU/mL, 10,000 mIU/mL, 100,000 mIU/mL and 1,000,000 mIU/mL. The results demonstrated that no hook effect was observed at hCG concentration up to 1,000,000 mIU/mL.

d. Stability

The iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip have been verified for shelf-life stability for 24 months at both 36ºF - 86ºF (2°C - 30°C).

e. Specificity and cross reactivity

Specificity study to determine false-positive result rate

To evaluate specificity, 300 urine samples were collected from normal, non-pregnant pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old) and post-menopausal (>55 years old). 100 people for each age group. Each urine sample was tested with iHealth® Early Pregnancy Test Strip format, iHealth® Early Pregnancy Test Stick format (dip method and midstream method). No false positive results were observed for any of the age groups.

Effect of cross reactivity

To evaluate cross-reactivity, negative and positive urine samples (0 and 10 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.

Effect of hCG β -core fragment (hCG β cf)

To evaluate the effect of the hCG β-core fragment, negative and positive urine samples (0 and 10 mIU/mL hCG) were spiked with hCG β-core fragment at concentrations of 0 pmol/L, 250,000 pmol/L, 500,000 pmol/L and 1,000,000 pmol/L. The performance of iHealth® Early Pregnancy Test was not affected by hCG β-core fragment concentrations up to 1,000,000 pmol/L.

f. Interfering substance

Interference from exogenous and endogenous substances

To evaluate the effect of the potential interfering substance, negative and positive urine samples (0 and 10 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:

Substances	Concentration
Acetaminophen	20mg/dL
Acetoacetic Acid	500mg/dL
Acetylsalicylic Acid	20mg/dL
Albumin	2000mg/dL
Ampicillin	20mg/dL
Ascorbic Acid	20mg/dL
Atropine	20mg/dL
Benzoylecgonine	10mg/dL

B-hydroxybutyrate	1000mg/dL
Bilirubin	2mg/dL
Caffeine	20mg/dL
Cannabinol	10mg/dL
Codeine	6μg/dL
EDTA	80mg/dL
Estriol-17-beta	1400μg/dL
Ethanol	1.00%
Gentisic Acid	20mg/dL
Glucose	2000mg/dL
Hemoglobin	500mg/dL
Ketone	20mg/dL
Methanol	10%
Phenothiazine	20mg/dL
Phenylpropanolamine	20mg/dL
Pregnanediol	1500μg/dL
Salicylic Acid	20mg/dL
Tetracycline	20mg/dL
Thiophene	20mg/dL

Effect of urine pH

To evaluate the effect of urine pH, negative and positive urine samples (0 and 10 mIU/mL hCG) were tested at pH values of 4, 5, 6, 7, 8 and 9. The results demonstrate that pH ranging from 4.0~9.0 in urine samples does not affect the performance of iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip.

Effect of urine specific gravity

To evaluate the effect of urine specific gravity, negative and positive urine samples (0 and 10 mIU/mL hCG) were tested at urine specific gravity of 1.000, 1.005, 1.015, 1.030 and 1.035. The results demonstrate that urine with a relative specific gravity ranging from 1.000 to 1.035 does not affect the performance of iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip.

B. Comparison study

a. Method comparison study

The performance of the new device was compared to the predicate device. A total of 204 pregnant and non-pregnant subjects collected samples and completed the study to obtain

a valid result. 109 were positive samples and 95 were negative samples. All samples were tested with candidate and predicate devices by professionals.

The results are summarized in the table below:

iHealth® Early Pregnancy Test Strip format (dip method)

Candidate Device		Predicate device		
		Positive	Negative	total
iHealth® Early Pregnancy Test Strip	Positive	54	0	54
	Negative	0	49	49
	total	54	49	103

iHealth® Early Pregnancy Test Stick format (dip and midstream methods)

Candidate Device		Predicate device		
		Positive	Negative	total
iHealth® Early Pregnancy Test	Positive	55	0	55
	Negative	0	46	46
	total	55	46	101

The conformity between the candidate device (iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip) and the predicate device is 100%.

b. Lay user study

Lay User Study

A total of 204 pregnant and not pregnant women subjects with diverse educational and professional backgrounds and ages between 18 and 55 years old participated in the Lay User Study. Each subject tested her own urine sample using iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip according to the labeling and provided a sample for professional testing.

The results are summarized in the table below:

iHealth® Early Pregnancy Test Strip format (dip method)

Candidate Device		Professional		
		Positive	Negative	total
Lay user	Positive	54	0	54
	Negative	0	49	49
	total	54	49	103

iHealth® Early Pregnancy Test Stick format (dip and midstream methods)

Candidate Device		Professional		
		Positive	Negative	total
Lay user	Positive	55	0	55
	Negative	0	46	46
	total	55	46	101

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

Each lay user was given a questionnaire to assess the comprehensibility 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.

Lay User Spiked Standard

The second lay user study was conducted with a total of 100 women with diverse educational and professional backgrounds between the ages of 18 years to 55. Lay users performed the testing using samples spiked with 0, 2, 3, 5, 10 and 15 mIU/mL hCG using iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip. Results were summarized below.

iHealth® Early Pregnancy Test Strip format

Sample number	hCG concentration	Lay users Results		% positive
		Number of positive	Number of negative	
B	0 mIU/mL	0	100	0%
A	2 mIU/mL	0	100	0%
E	3 mIU/mL	0	100	0%
D	5 mIU/mL	46	54	46%
F	10 mIU/mL	100	0	100%
C	15 mIU/mL	100	0	100%

iHealth® Early Pregnancy Test Stick format (dip method)

Sample number	hCG concentration	Lay users Results		% positive
		Number of positive	Number of negative	
B	0 mIU/mL	0	100	0%
A	2 mIU/mL	0	100	0%
E	3 mIU/mL	0	100	0%

D	5 mIU/mL	43	57	43%
F	10 mIU/mL	100	0	100%
C	15 mIU/mL	100	0	100%

iHealth® Early Pregnancy Test Stick format (simulated midstream method)

Sample number	hCG concentration	Lay users Results		% positive
		Number of positive	Number of negative	
B	0 mIU/mL	0	100	0%
A	2 mIU/mL	0	100	0%
E	3 mIU/mL	0	100	0%
D	5 mIU/mL	44	56	44%
F	10 mIU/mL	100	0	100%
C	15 mIU/mL	100	0	100%

C. Other clinical study

Detection of hCG in Early Pregnancy Clinical Samples

Early pregnancy urine samples from day -8 to day +1 of their expected period were collected. The early pregnancy urine samples of each day from 83 subjects were tested using iHealth® Early Pregnancy Test Strip format and iHealth® Early Pregnancy Test Stick format (dip method and midstream method).

The results are summarized in the table below:

iHealth® Early Pregnancy Test Strip format

Day relative to EMP	Day relative to Missed Period	Percent Pregnant Result(%)	Number Pregnant Result	Number Not Pregnant Result	Total Samples
-8	-9	5%	4	79	83
-7	-8	13%	11	72	83
-6	-7	28%	23	60	83
-5	-6	78%	65	18	83
-4	-5	93%	77	6	83
-3	-4	99%	82	1	83
-2	-3	99%	82	1	83
-1	-2	100%	83	0	83

0	-1	100%	83	0	83
+1	0	100%	83	0	83

iHealth® Early Pregnancy Test Stick format (dip method)

Day relative to EMP	Day relative to Missed Period	Percent Pregnant Result(%)	Number Pregnant Result	Number Not Pregnant Result	Total Samples
-8	-9	5%	4	79	83
-7	-8	12%	10	73	83
-6	-7	27%	22	61	83
-5	-6	78%	65	18	83
-4	-5	93%	77	6	83
-3	-4	99%	82	1	83
-2	-3	99%	82	1	83
-1	-2	100%	83	0	83
0	-1	100%	83	0	83
+1	0	100%	83	0	83

iHealth® Early Pregnancy Test Stick format (midstream method)

Day relative to EMP	Day relative to Missed Period	Percent Pregnant Result(%)	Number Pregnant Result	Number Not Pregnant Result	Total Samples
-8	-9	6%	5	78	83
-7	-8	13%	11	72	83
-6	-7	27%	22	61	83
-5	-6	78%	65	18	83
-4	-5	93%	77	6	83
-3	-4	99%	82	1	83
-2	-3	99%	82	1	83
-1	-2	100%	83	0	83
0	-1	100%	83	0	83
+1	0	100%	83	0	83

8. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that iHealth® Early Pregnancy Test and iHealth® Early Pregnancy Test Strip are substantially equivalent to the predicate device.