August 20, 2020

Acon Laboratories Inc.
Qiyi Xie
Senior Officer, Clinical & Regulatory Affairs
5850 Oberlin Drive #340
San Diego, CA 92121

Re: K193318
Trade/Device Name: Distinct® Early Detection Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: July 22, 2020
Received: July 23, 2020

Dear Qiyi Xie:

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 (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 located 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.

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

803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k193318

Device Name

Distinct® Early Detection Pregnancy Test

Indications for Use *(Describe)*

The Distinct® Early Detection Pregnancy Test is an aid for the early detection of pregnancy intended for home use. The device is a chromatographic immunoassay that performs qualitative detection of human chorionic gonadotropin (hCG) in urine. This test can help determine pregnancy as early as 6 days before the day of the missed period (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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is k193318

Submitter's Identification:

ACON Laboratories, Inc.
5850 Oberlin Drive, # 340
San Diego, California 92121
Tel.: 858-875-8019
Fax: 858-875-8011

Date Prepared: August 18, 2020

Contact Person:

Qiyi Xie
Senior Officer, Regulatory & Clinical Affairs
Email: qxie@aconlabs.com

Proprietary Name of the Device:

Distinct® Early Detection Pregnancy Test

Common Name:

Over the counter Pregnancy Test

Classification Name:

21 CFR § 862.1155 Human chorionic gonadotropin (HCG) test system

Product Code:

LCX

Device Description:

The Distinct® Early Detection Pregnancy Test is a rapid chromatographic immunoassay for in vitro qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. It is for self-testing. The test strip and absorbent tip are assembled in a plastic housing. The test strip contains monoclonal anti-hCG antibodies and goat anti-mouse polyclonal antibodies. The test result is shown in the result window and read visually after 3 minutes of urine application.

A blue sign of plus (+) at the test window indicates that hCG has been detected (pregnant). Absence of the plus (+) and only a blue line (-) in the Test Window suggests no hCG has been detected. To serve as a procedural control, a blue line will always appear in the Control Window indicating that proper volume of specimen has been added and membrane wicking has occurred.

Intended Use:

The Distinct® Early Detection Pregnancy Test is an aid for the early detection of pregnancy intended for home use. The device is a chromatographic immunoassay that performs qualitative detection of human chorionic gonadotropin (hCG) in urine. This test can help determine pregnancy as early as 6 days before the day of the missed period (5 days before the day of the expected period).

Test Principle:

The assay is conducted by applying urine specimen to the absorbent tip of the test. The specimen migrates via capillary action from absorbent tip to the test strip. If urine contains hCG, hCG will form a sandwich binding with particles labeled hCG monoclonal antibody and the hCG monoclonal antibody pre-coated on strip to form a blue sign of Plus (+) in Test Window. If urine does not contain hCG, absence of the plus (+) and only a blue line (-) in the test window. In Control Window, particles labeled with mouse IgG will bind pre-coated goat anti-mouse IgG to form a blue Control Line.

Comparison to the predicate device:

Area of Comparison	***Candidate Device***	***Predicate Device***
	Distinct® Early Detection Pregnancy Test (k193318)	FIRST RESPONSE™ Early Result Pregnancy Test (k123436)
Similarities		
Indications for Use	The Distinct® Early Detection Pregnancy Test is an aid for the early detection of pregnancy intended for home use. The device is a chromatographic immunoassay that performs qualitative detection of human chorionic gonadotropin (hCG) in urine. This test can help determine pregnancy as early as 6 days before the day of the missed period (5 days before the day of the expected period).	The FIRST RESPONSE ™ Early Result Pregnancy Test is an over the counter Chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.
Product Code/Regulation Number	LCX/21 CFR 862.1155	**Same**
Regulation Description	Human chorionic gonadotropin (HCG) test system	Same
Detection Time	Early detection of pregnancy; 5 days before the expected period (6 days before the day of the missed period)	Same
Patient Use	Over the counter use/self-testing	Same

Intended Specimen	Urine	Same
Usage Type	Single -use	Same
Assay Technique	Immunochromatographic Assay	Same
Test Result	Qualitative	Same
Antigen Specificity	hCG β-core fragment	Same
Dose Hook Effect	No Dose-Hook effect was observed at 1000,000 mIU/ml	Same
Sample Collection Method	Midstream method, dip method	Same
Sample Application Time	5-10 seconds	5 seconds
Reading Time	3 – 10 minutes	3 minutes
Storage Temperature	2- 30°C	< 30°C
Accuracy	>99%	Same
Differences		
Positive Result Display	A blue vertical line and a blue horizontal line in the test window, a blue line in the control window.	Two pink lines in the test window
Traceability	WHO 5th International standard for hCG	WHO 4th International standard for hCG

Discussion of Performance Tests Performed:

1.*Analytical Performance*

a. Precision/Reproducibility:

The purpose of this study is to determine the reproducibility of Distinct® Early Detection Pregnancy Test when performed by lay users. Thirty negative urine specimens were collected and spiked with WHO 5th International hCG standard to the following concentrations: 3, 5, 6, 7.5, 8, 8.5, 10, 12, 15 and 25 mIU/ml. The samples were blinded and randomized prior to being read. A total of 300 lay users performed the test using three lots of the devices. The results demonstrated that 100% of the samples were positive at 10 mIU/mL hCG and higher using both the dip and midstream methods.

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

c. Traceability and Stability:

Traceability:

The test is calibrated against the WHO 5th International Standard (IS) for Chorionic Gonadotrophin (hCG).

Stability

The shelf life of Distinct® Early Detection Pregnancy Test was verified by accelerated, open pouch and on-going real – time stability studies which confirmed the claimed shelf life of 24 months.

d. Analytical specificity:

Cross Reactivity

The purpose of this study is to determine if Distinct® Early Detection Pregnancy Test has cross reaction with relative substances, such as LH, FSH and TSH. Results of the study showed no cross reactivity with 1000 mIU/mL FSH, 1000 μIU/mL TSH and 1000 mIU/mL LH.

Interference

The purpose of this study is to evaluate the effect of potentially interfering substances commonly found in human urine on Distinct® Early Detection Pregnancy Test. Results of the study demonstrated that none of the endogenous or exogenous substances tested interfered with the expected results.

Effects of Urine pH

The purpose of this study is to determine the effect of urine pH on Distinct® Early Detection Pregnancy Test. From the results of the study, it was concluded that the pH of the samples, when tested from a range pH 4 to pH 9 did not interfere with the performance of Distinct® Early Detection Pregnancy Test.

Specific Gravity

The purpose of this study is to determine the effect of urine specific gravity on Distinct® Early Detection Pregnancy Test. From the results of the study, it was concluded that the different urinary specific gravity over the range of 1.003 – 1.035 does not influence the results of Distinct® Early Detection Pregnancy Test.

High Dose Hook Effect Study

The purpose of this study is to evaluate if there is a hook effect causing false negative results at high hCG concentrations. hCG concentrations of 500, 1000, 10,000, 100,000, 500,000, and 1,000,000 mIU/mL were tested and no hook effect was observed.

Effects of hCG β-Core Fragment

The purpose of this study is to evaluate if there is a hook effect causing false negative results due to high concentrations of hCG β-Core Fragment. Concentrations of β-Core Fragment up to 1,000,000 pmol/L were tested and no hook effect was observed.

2. *User Performance Study*

The purpose of the user comparison study was to determine if the Distinct® Early Detection Pregnancy Test can be performed correctly by laypersons. A total of 205 laypersons tested their own urine with approximately half using the dip method and half using the midstream method. The lay user results were compared to results from the same sample performed with the predicate device. Results are summarized below:

Candidate device (layperson) vs. predicate device (professional)

Urine stream Method		Predicate (Professional)		
		Pos	Neg	Total
Candidate (Layperson)	Pos	51	0	51
	Neg	0	51	51
	Total	51	51	102

Urine Dipping Method		Predicate (Professional)		
		Pos	Neg	Total
Candidate (Layperson)	Pos	52	0	52
	Neg	0	51	51
	Total	52	51	103

The study results indicate that the Distinct® Early Detection Pregnancy Test can be performed by laypersons correctly and it is easy to use. The accuracy is over 99%.

3. Device performance in different age groups

The purpose of the study is to determine the incidence of positive test results using the candidate device among non-pregnant women in three age groups: 18-40, 41-45, and 55 and older. A total of 300 subjects provided samples with 100 for each age group. Three lots of the candidate device were used for this study. No positive results were observed for any of the age groups..

4. Detection of hCG in Early Pregnancy Clinical Samples

The purpose of the study is to determine how soon before the expected menstrual period (EMP) the candidate device can detect pregnancy. Urine from 65 non-pregnant women expecting to become pregnant were collected daily starting 8 days prior to their expected period through the date of their expected menstrual period (EMP), as well as the 6th or 7th day after their EMP. Results are summarized

below:

Time Point	Number of Positive	Number of Negative	% Positive
EMP +6 or 7 days	65	0	100.0%
EMP	65	0	100.0%
EMP-1 day	65	0	100.0%
EMP-2 days	65	0	100.0%
EMP-3 days	63	2	96.9%
EMP-4 days	61	4	93.8%
EMP-5 days	49	16	75.4%
EMP-6 days	32	33	49.2%
EMP-7 days	13	51	20.3%
EMP-8 days	6	54	10.0%

Conclusion:

The laboratory testing results, and clinical studies demonstrate that the Distinct® Early Detection Pregnancy Test is substantially equivalent to the FIRST RESPONSE™ Early Result Pregnancy Test cleared under k123436 .