February 2, 2018

ACRO Biotech, Inc.
% Feng-Yu Lee
Principal Regulatory Consultant
IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675

Re: K172512
Trade/Device Name: ACRO HCG Pregnancy Rapid Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: January 12, 2018
Received: January 26, 2018

Dear Feng-Yu Lee:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
k172512

Device Name
ACRO HCG Pregnancy Rapid Test

Indications for Use *(Describe)*
The ACRO hCG Pregnancy Rapid Test is used by the consumer for the visual qualitative detection of Human Chorionic Gonadotropin (hCG) in urine. It is used to detect the pregnancy of HCG in urine as an indication 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k172512

1. Submitter's Identification:

Acro Biotech, Inc
9500 Seventh Street, Suite M
Rancho Cucamonga, CA 91730
Phone Number: 1-909-4666892
FAX Number: 1-909-4666892

c/o IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
Phone Number: 1-949-218-0929
Fax Number: 1-949-218-0928

Date Summary Prepared: February 2nd, 2018

2. Name of the Device:
ACRO HCG Pregnancy Rapid Test,

3. Common or Usual Name: Blood Glucose Monitoring System

Product Code	Classification	Regulation Section	Panel
LCX; Kit, Test, Pregnancy, HCG, Over-the-Counter	Class II	21 CFR 862.1155 Human Chorionic Gonadotropin (HCG) test system	Clinical Chemistry 75

4. Device Description:

The ACRO HCG Pregnancy Rapid Test is designed to be tested in midstream mode. The ACRO HCG Pregnancy Rapid Test consists of a single test strip encased in plastic device housing, with or without an additional absorbent tip. The result is generated by immersing the tip in the urine stream for a sufficient amount of time to absorb an adequate sample volume. It is a rapid, one-step chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG.

5. Intended Use:

The ACRO hCG Pregnancy Rapid Test is used by the consumer for the visual qualitative detection of Human Chorionic Gonadotropin (hCG) in urine. It is used to detect the pregnancy of HCG in urine as an indication of pregnancy.

6. Predicate Device Information:

The subject devices are substantially equivalent to the brand of Rightest Blood Glucose Monitoring System noted below.

Name: MiniStick Pregnancy Test
Device Company: ACRO Biotech, Inc.
510(K) Number: K960733

7. Comparison to Predicate Devices:

The ACRO HCG Pregnancy Rapid Test is a modified model of a cleared device, the MiniStick Pregnancy Test, k960733. The changes to the cleared device include addition of an absorbent tip, result reading time and device storage condition.
There is no change to the indications for use nor to the fundamental scientific technology of the device.

Substantial Equivalence Comparison

Similarities		
Item	**Candidate**	**Predicate Device (k960733)**
Intended Use	Rapid qualitative detection of hCG to aid in the early detection of pregnancy.	Same
Cutoff	25 mIU/ml	Same
Test Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Positive result	2 colored lines	Same
Negative result	1 colored line	Same
Detection reagent	Colloidal gold	Same
Specificity	Negative at: hLH: 500mIU/ml hFSH: 1000mIU/mL hTSH: 1000 μIU/mL	Same
Traceability	WHO 4th International Standard	Same
Critical Raw Materials (source) and Preparation Formulas	Antibody and Antigen Nitrocellulose Membrane Colloidal Gold Conjugate Pad Sample Pad	Same
Component Strip	Width and Length	Same
Critical Production Process	Membrane spray/coating Conjugate Pad Sample pad treatment	Same

Differences		
Storage Temperature	35 - 86°F (2 – 30 °C)	Below 86°F (30 °C)
Read time	3 to 10 minutes	After 5 minutes
Device Format	Midstream without Absorbent Tip and Midstream with Absorbent Tip	Midstream without Absorbent Tip

8. Summary of Verification and Validation activities
Lay user performance, Precision, Time Flex, Storage and Stability Studies were conducted and passed acceptance criteria to support the changes.

9. Conclusions from Verification and Validation Activities:

The results of all verification and validation activities demonstrate that the candidate device is substantially equivalent to the cleared predicate MiniStick Pregnancy Test (k960733). The differences between the modified device and the cleared predicate device do not raise any new issue of safety and effectiveness.