DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

June 17, 2016

Alere Scarborough, Inc.
Angela Drysdale
VP Regulatory & Clinical Affairs - Infectious Disease
10 Southgate Road
Scarborough, ME 04074

Re: K161364
Trade/Device Name: BinaxNOW® G6PD Test
Regulation Number: 21 CFR 864.7360
Regulation Name: Erythrocytic glucose-6-phosphate dehydrogenase assay
Regulatory Class: Class II
Product Code: JBF
Dated: May 17, 2016
Received: May 18, 2016

Dear Ms. Drysdale:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161364

Device Name
BinaxNOW® G6PD Test

Indications for Use *(Describe)*

The BinaxNOW® G6PD (Glucose-6-Phosphate Dehydrogenase) Test is an in vitro enzyme chromatographic test for the qualitative detection of G6PD enzyme activity in human venous whole blood, collected in heparin or ethylenediaminetetraacetic acid (EDTA). The BinaxNOW® G6PD Test is a visual screening test used for differentiating normal from deficient G6PD activity levels in whole blood and is intended to aid in the identification of people with G6PD deficiency. Samples which generate deficient results should be assayed using a quantitative G6PD test method to verify the deficiency.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K161364

SUBMITTER
Alere Scarborough, Inc.
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Establishment Registration Number: 1221359

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DATE PREPARED
06/13/2016

TRADE NAME
BinaxNOW® G6PD Test

COMMON NAME
BinaxNOW® G6PD Test, BinaxNOW® G6PD

CLASSIFICATION NAME
Erythrocytic glucose-6-phosphate dehydrogenase assay. (per 21 CFR 864.7360)

CLASSIFICATION
Class II

PRODUCT CODE
JBF

PANEL
Hematology

PREDICATE DEVICES
BinaxNOW® G6PD Test, K080003

DEVICE DESCRIPTION

The BinaxNOW® G6PD test device consists of a lateral flow test strip comprised of a white sample pad and a reaction pad, which is located at the top of the strip. The reaction pad contains the reagents necessary for the G6PD enzymatic reaction and the subsequent reduction of a nitro blue tetrazolium dye into its concomitant blue formazan product. The resulting color change on the strip indicates enough G6PD activity is present to presume the sample is not deficient.

To perform the test, a whole blood sample is mixed with red blood cell (RBC) lysing reagent in a sample preparation vial and then transferred to the test device sample pad. The lysed blood sample migrates up the test strip, reconstituting reagents in the reaction pad. When the sample front (or liquid migration) covers the entire reaction pad, the device is closed.

Test results are read visually. If no change in the red color of the sample front is observed at the test read time, the sample is presumed to be deficient in G6PD enzyme activity. Samples normal in G6PD activity produce a distinct color change – the red sample color changes to a brown / black color on the upper half of the reaction pad.

INTENDED USE

The BinaxNOW® G6PD (Glucose-6-Phosphate Dehydrogenase) Test is an *in vitro* enzyme chromatographic test for the qualitative detection of G6PD enzyme activity in human venous whole blood, collected in heparin or ethylenediaminetetraacetic acid (EDTA). The BinaxNOW® G6PD Test is a visual screening test used for differentiating normal from deficient G6PD activity levels in whole blood and is intended to aid in the identification of people with G6PD deficiency. Samples which generate deficient results should be assayed using a quantitative G6PD test method to verify the deficiency.

TECHNOLOGICAL CHARACTERISTICS

The BinaxNOW® G6PD Test uses lateral flow, enzyme chromatography technology using visual determination for qualitative test results of G6PD deficiency in whole blood.

PERFORMANCE SUMMARY

Clinical Performance – BinaxNOW® G6PD Test Method Comparison

The performance of the BinaxNOW® test was compared to a commercially available quantitative G6PD test in a prospective study conducted in 2007-2008 in the U.S. Both heparinized and EDTA whole blood specimens were collected from 246 subjects and were evaluated on the BinaxNOW® test.

All of the samples that generated a value less than or equal to 2.0 U/gHb on the comparative method generated deficient results on the BinaxNOW® G6PD test.

The percent agreement analyses and 95% confidence intervals for the BinaxNOW® G6PD test results for detection of G6PD enzyme activity deficiency, as compared to the comparative method, on both heparinized and EDTA blood samples, is provided below. For both sample types, a comparative method cut-off value of 4.2 U/gHb was used in the analysis. For all results less than or equal to 4.2 U/gHb on the comparative method, a deficient BinaxNOW result was considered a correct result. Likewise, for all

comparative method results greater than 4.2 U/gHb, a normal BinaxNOW® result was considered a correct result.

% AGREEMENT WITH HEPARIN SAMPLES:

		Comparative Method →	
		Deficient	Normal
BinaxNOW®	Deficient	48	4
Test →	Normal	1	190

"Deficient result" percent agreement = 48 / 49 = 98.0% (CI = 89.3 - 99.6%)
"Normal result" percent agreement = 190 / 194 = 97.9% (Cl = 94.8 - 99.2%)
Overall percent agreement = 238 / 243* = 97.9% (Cl = 95.3 - 99.1%)
(* 3 invalid tests)

% AGREEMENT WITH EDTA SAMPLES:

		Comparative Method →	
		Deficient	Normal
BinaxNOW®	Deficient	49	5
Test →	Normal	1	191

"Deficient result" percent agreement = 49 / 50 = 98.0% (CI = 89.5 - 99.6%)
"Normal result" percent agreement = 191 / 196 = 97.4% (Cl = 94.2 - 98.9%)
Overall percent agreement = 240 / 246 = 97.6% (CI = 94.8 - 98.9%)

Additionally, BinaxNOW® test results on the heparin samples were the same as the results on the EDTA samples for 240 of the 243 subjects, whose samples generated valid results on both sample types, yielding a percent agreement of 99%.

Interfering Substances

The BinaxNOW® G6PD test was evaluated for possible interference from high levels of endogenous blood components. Whole blood samples were tested that contained bilirubin (conjugated and unconjugated), triglycerides, total cholesterol, lactic acid, lactate dehydrogenase, or glucose at concentrations above physiological levels. None of the endogenous blood components affected test performance. The presence of an elevated level of copper sulfate, which is known to inhibit G6PD enzyme activity, was also evaluated and did not affect test performance.

Blood samples with abnormally low and high hematocrit levels (17-18% and 54-65% respectively) were evaluated, and test performance was affected as described in the Limitations section of the package insert.

Reproducibility Study – Multiple Operators

A blind study of the BinaxNOW® G6PD Test was conducted at 3 separate sites using panels of blind coded specimens, which included G6PD normal and deficient samples. Participants tested each sample multiple times on 3 different days. There was 98.4% (123/125) agreement with expected test results, with no significant differences within run (replicates tested by one operator), between run (3 different days), between sites (3 sites), or between operators (6 operators).

Precision Study – Single Operator

Blood samples from two individuals were drawn into both EDTA and heparin collection tubes, and all 4 samples were tested in duplicate on the BinaxNOW® test on ten successive days by a single operator. The samples collected from one individual were interpreted as normal 100% of the time. The samples collected from the other individual were interpreted as deficient 100% of the time.

The results of the analytical and clinical studies performed with the BinaxNOW® G6PD Test support the determination of substantial equivalence in accordance with the stated intended use and device labeling.