September 14, 2022

Baebies, Inc.
Candice Prowse
Regulatory Affairs Specialist
615 Davis Drive
Suite 800
Morrisville, North Carolina 27560

Re: K201049
Trade/Device Name: FINDER G6PD Test
Regulation Number: 21 CFR 864.7360
Regulation Name: Erythrocytic Glucose-6-Phosphate Dehydrogenase Assay
Regulatory Class: Class II
Product Code: JBF
Dated: September 14, 2022
Received: June 17, 2022

Dear Candice Prowse:

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,

Min Wu
Branch Chief
Division of Immunology and Hematology 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)*
K201049

Device Name
FINDER G6PD

Indications for Use *(Describe)*
The FINDER G6PD test is intended for semi-quantitative measurement of glucose-6-phosphate dehydrogenase in venous whole blood specimens collected in lithium heparin tubes, for the identification of G6PD deficient samples.
The FINDER G6PD test is intended to be used with the FINDER Instrument in point of care or clinical laboratory settings.

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

[In accordance with 21 CFR 807.92]

Baebies, Inc.

FINDER® G6PD Test

1. Submitter / 510(k) Holder

Baebies Inc., 25 Alexandria Way, Durham, NC 27703, USA
Main phone number: (919) 891-0432
Main fax number: (919) 328-8402

Contact Person: Candice Prowse, Director of Regulatory Affairs and Clinical Affairs

Date Prepared: September 12, 2022

2. Device

Proprietary Name:	FINDER G6PD Test
510(k) Number	K201049
Classification Name:	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Quantitative
Classification Panel:	Hematology
Classification:	Class II
Classification Regulation:	21 CFR 864.7360
Product Code:	JBF

3. Predicate Device

Class	Manufacturer	510(k) Number	Device Name/Description
II	Pointe Scientific, Inc.	K024006	Glucose-6-Phosphate Dehydrogenase (G6PD) Reagent Set

4. Device Description

The FINDER G6PD test system measures G6PD quantitatively from a 50µL venous whole blood specimen. The blood specimen should be collected in lithium heparin anticoagulant. The G6PD test system is suitable for use in both a point-of-care setting and a clinical laboratory. The time to result is around 16 minutes from sample introduction.

The FINDER G6PD test system consists of the following main components.

1. FINDER G6PD Test Cartridge – The FINDER Cartridge uses electrowetting-based digital microfluidics to integrate and automate all the sample and reagent handling steps required to perform the G6PD test. The cartridge is single-use and contains all the reagents necessary to perform the test.

2. FINDER Instrument – The FINDER Instrument contains all the hardware and software required to operate the FINDER Cartridge. The instrument provides electrowetting control, thermal control and detection capability, required to perform the G6PD test. The instrument also provides a touch-screen user interface and software necessary to perform the test and report results.

4.1. Accessories

The following accessories have not received prior 510(k) clearance.

The FINDER System includes a 50µL fixed-volume micropipette used to transfer specimens from the specimen collection device to the FINDER Cartridge for testing.

The FINDER system includes an optional thermal printer that is connected to the instrument via USB.

4.2. Test Principle

G6PD activity is measured from a whole blood sample input. Red blood cells are lysed osmotically in the cartridge by combining whole blood with water. The lysed blood cells are then incubated with β-nicotinamide adenine dinucleotide phosphate (NADP) and glucose-6-phosphate (G6P), resulting in the production of NADPH. Kinetic fluorescence measurements are used to quantify the rate of NADPH production, which is proportional to G6PD enzymatic activity. The reaction occurs in the presence of maleimide, which is used to improve the specificity of the test by inhibiting the production of NADPH from 6-phosphogluconate dehydrogenase. Hemoglobin present in the lysed sample is measured by absorbance and used to normalize G6PD enzymatic activity, resulting in a final reported unit of U/gHb.

$$G6P + NADP^{+} \xrightarrow{G6PD} 6 - PG + NADPH + H^{+}$$

The FINDER G6PD Test reports the hemoglobin normalized G6PD activity in U/gHb and as a % of the site-specific Adjusted Male Median (AMM). The site-specific AMM is calculated using a minimum of 36 normal male samples and can be set by the user.

5. Indications for Use

The FINDER G6PD test is intended for semi-quantitative measurement of glucose-6-phosphate dehydrogenase in venous whole blood specimens collected in lithium heparin tubes, for the identification of G6PD deficient samples.

The FINDER G6PD test is intended to be used with the FINDER Instrument in point of care or clinical laboratory settings.

The Indications for Use statement of the predicate is substantially the same as the candidate device. Any differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

6. Comparison of Technological Characteristics with Predicate

The FINDER G6PD test is intended for use on the FINDER Instrument. The similarities and differences between the FINDER G6PD Test and its predicate are presented in the following Table 1.

Table 1 - FINDER G6PD versus Pointe Scientific G6PD Reagent Set

Characteristic	Predicate Pointe Scientific Glucose-6-Phosphate Dehydrogenase (G6PD) Reagent Set K024006)	FINDER G6PD Test
Regulation	21 CFR 864.7360	Same
Regulation Name	Erythrocytic glucose-6-phosphate dehydrogenase assay	Same
Procode	JBF	Same
Intended Use	For the quantitative determination of glucose-6-phosphate dehydrogenase (G6PD) in blood at 340 nm. For in vitro diagnostic use only.	The FINDER G6PD test is intended for semi-quantitative measurement of glucose-6-phosphate dehydrogenase in venous whole blood specimens collected in lithium heparin tubes, for the identification of G6PD deficient samples. The FINDER G6PD test is intended to be used with the FINDER Instrument in point of care or clinical laboratory settings

Characteristic	Predicate Pointe Scientific Glucose-6-Phosphate Dehydrogenase (G6PD) Reagent Set K024006)	FINDER G6PD Test
Class	II	Same
Device Panel	Hematology	Same
Analyzer	Cobas Mira	FINDER Instrument
Assay Manufacturer	Pointe Scientific	Baebies, Inc.
Analytes	G6PD	Same
Linear Range	2.78 to 20.69 U/g Hb	0.8 to 19.7 U/g Hb
Limit of Blank	Not specified	0.2 U/g Hb
Sensitivity (Limit of Detection)	0.4 U/g Hb	0.4 U/g Hb
Limit of Quantitation	Not specified	1.1 U/g Hb
Specimen	Whole blood	Same
Method	NADPH kinetic spectrophotometric method	NADPH kinetic fluorometric method
Component Reagent matrices	G6P, Buffer, NADP and Maleimide	G6P, Buffer, NADP and Maleimide
Reagent Format	Dry and liquid, ready to use reagents; manual reconstitution	Dry test-specific reagents and liquid diluent and filler fluid; reconstitution performed by instrument
Detection of analyte, Measurand	Spectrophotometric, quantitative at 340nm	Fluorimetric, semi-quantitative 370nm Excitation/460nm Emission

Characteristic	Predicate Pointe Scientific Glucose-6-Phosphate Dehydrogenase (G6PD) Reagent Set K024006)	FINDER G6PD Test
		The FINDER G6PD Test reports the hemoglobin normalized G6PD activity in U/gHb and as a % of the site-specific Adjusted Male Median (AMM).
Hemoglobin	Reaction with potassium cyanide	Absorbance at 524nm
Controls	Hemolysate	Same
Calibration Traceability	Absorptivity of NADPH	NADPH extinction coefficient of $6.3 mM^{-1} cm^{-1}$

7. Performance Testing Summary

7.1. Nonclinical Performance

7.1.1. Precision

Two precision studies (internal and external) were performed to evaluate the repeatability and reproducibility precision of the FINDER G6PD test. Precision was evaluated in accordance with the CLSI EP05-A3 guideline.

The single site precision study was conducted at one site over a period of 21 non-consecutive days with 2 sessions per day and 2 runs per session. A session was defined as a batch of multiple runs where each session was separated by at least two hours. A run was defined as a single instance of a sample being tested. Results were determined using three levels of hemolysate control samples (low = 1.4 U/gHb, medium = 7.0 U/gHb, high = 17.4 U/gHb) resulting in 84 replicates per level. The study was conducted on 3 instruments using 3 cartridge lots.

The reproducibility study was conducted at 3 sites using fresh whole blood samples that were prepared each of 5 days by appropriate dilution to obtain 3 target G6PD levels (low = < 2.0 U/g Hb, medium = 3.0 – 5.0 U/g Hb, and high = > 8.0 U/g Hb) per day. Each day aliquots at the three sample levels were delivered to each testing site, where they were subdivided into 8 samples that were evaluated on 2 instruments by 2 operators, with 2 replications each. A total of 15 samples (3 G6PD levels, prepared on each of 5 days) were evaluated, and each sample was measured by the FINDER Instrument 24 times (across 3 sites, 2 instruments, 2 operators per site, 2 replicates), resulting in a total of 360 measurements for analysis.

Results of the precision studies are shown below are shown in Table 2 and Table 3.

Sample	N	Mean (U/gHb)	Between Run (%CV)	Between Day (%CV)	Between Operator (%CV)	Between Lot (%CV)	Between Instrument (%CV)	Repeatability (%CV)	Reproducibility (%CV)
Low	84	1.4	3.2%	0.7%	0.0%	0.0%	3.8%	4.1%	6.5%
Inter.	84	7.0	2.2%	1.1%	0.0%	1.8%	2.4%	3.6%	5.3%
High	84	17.4	2.6%	0.0%	0.0%	0.0%	3.9%	2.4%	5.2%

Table 2 – Summary of Single Site Precision Study

Sample	N	Mean (U/gHb)	Between Site (%CV)	Between Instrument (%CV)	Between Operator (%CV)	Repeatability (%CV)	Reproducibility (%CV)
Low	120	1.1	0.0%	0.9%	0.0%	5.9%	6.0%
Inter.	120	3.5	0.7%	2.5%	1.0%	3.4%	4.4%
High	120	11.2	0.5%	0.6%	2.2%	6.6%	7.0%

Table 3 – Summary of Reproducibility Precision Study

7.1.2. Linearity

Linearity was evaluated in accordance with CLSI EP06-A. Two separate studies were conducted to evaluate linearity. The first study was a full range linearity study that used contrived samples of recombinant G6PD enzyme spiked into whole blood to achieve activity levels that cover the intended linear range of the test. Nine samples were generated with increasing levels of G6PD activity from 2.0 to 19.7 U/gHb.

The second study was a native linearity study that used whole blood from a normal and G6PD-deficient donor. The native linearity study was performed to ensure that linearity demonstrated in the full range linearity study with contrived samples is not an artifact associated with usage of recombinant G6PD. Nine samples were generated with increasing levels of G6PD activity from 0.8 to 13.9 U/gHb.

The linear range for the FINDER G6PD test is given by the full range of both linearity studies. The FINDER G6PD test was demonstrated to be linear from 0.8 to 19.7 U/g Hb.

7.1.3. Interference

Interference was evaluated in accordance with CLSI EP07 3rd edition guidelines. Whole blood test samples were spiked with possible interfering substances at concentrations equal to or greater than the guidelines. Each whole blood sample was tested at two G6PD enzymatic activity levels: normal G6PD activity (>7 U/gHb) and near the medical decision level (MDL near 2 – 4 U/gHb). Spiked samples (test pools) were compared to control pool without the interfering substances.

Hematocrit values greater than 40% did not interfere with the G6PD test result. A bias of -15.3% was observed for a normal sample at 29% hematocrit (8.9 g/dL hemoglobin on FINDER) as compared to the control pool of 50% hematocrit (15.3 g/dL hemoglobin on FINDER). A bias of -11.1% was observed for a sample near the medical decision level at 30% hematocrit (11.3 g/dL hemoglobin on FINDER). as compared to the control pool of 50% hematocrit (15.3 g/dL hemoglobin on FINDER).

The following endogenous substances were found to be non-interfering at the maximum tested concentrations.

Endogenous Substances:

Substance	Maximum Tested Concentration
Bilirubin	50 mg/dL
Hemoglobin	5 g/L
Intralipid	1000 mg/dL
Glucose	55 mM
Galactose	1 mM
Copper	0.150 mg/dL
Lactate	90 mg/dL
Lactate dehydrogenase	6000 U/L

The following common drugs were found to be non-interfering at the maximum tested concentrations.

Common Drugs

Substance	Maximum Tested Concentration
Ampicillin	0.16 mM
Ibuprofen	2.5 mM

7.1.4. Sensitivity

The Limit of Blank (LoB), Limit of Detection (LoD), and the Limit of Quantitation (LoQ) for the FINDER G6PD test were evaluated in accordance with CLSI EP17-A2.

The LoB was evaluated using whole blood altered to a blank G6PD activity; the LoD was evaluated using whole blood at low G6PD activity; the LoQ was evaluated using four whole blood samples with increasing levels of G6PD activity prepared by spiking a blank pool with increasing concentrations of a normal pool.

The studies were conducted using 3 lots of FINDER G6PD Cartridges on 6 FINDER Instruments.

Table 6 – Sensitivity (LoB, LoD, LoQ)

Detection Capability	G6PD (U/g Hb)
Limit of Blank (LoB)	0.2
Limit of Detection (LoD)	0.4
Limit of Quantitation (LoQ)	1.1

8. Clinical Performance

8.1. Method Comparison with Predicate Method

A clinical method comparison study was performed to demonstrate and compare the clinical performance of the FINDER Instrument and the FINDER G6PD Cartridge test to a comparator method using venous whole blood sample collected in lithium heparin tubes. The study design for this method comparison study was based on CLSI EP09-c – Measurement Procedure Comparison and Bias Estimation Using Patient Samples.

Lithium heparinized whole blood samples from 200 subjects were analyzed on the FINDER Instrument across 6 collection sites. Whole blood samples were shipped to a central laboratory under refrigerated conditions to analyze using the comparator method.

The samples tested were collected from 6 sites including one biorepository. Subjects included 89 males and 92 females with ages ranging from 20 to 72 years. 19 contrived samples were included in the study

G6PD activity results were compared using a Deming Regression linear fit yielding an estimated slope of 0.92, an intercept of 0.28, and a correlation coefficient of 0.9. The slope, intercept, and correlation coefficient are shown in the table below.

Measurand	N	Range	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient
G6PD	200	1.1 – 16.6 U/gHb	0.92 (0.89, 0.95)	0.28 (0.12, 0.44)	0.9

The bias and percentage bias at the medical decision levels are shown in the table below

MDLs	Bias (95% CI)	%Bias (95% CI)
3.1 U/gHb (30% of AMM)	0.0 U/gHb (-0.1, 0.2)	1.4% (-2.5%, 5.4%)
8.4 U/gHb (80% of AMM)	-0.4 U/gHb (-0.5, 0.2)	-4.3% (-6.5%, -2.0%)

A concordance analysis was performed where the first 36 normal male samples were used to calculate the adjusted male median. The remaining 167 samples were used in the data analysis. The adjusted male median for the FINDER G6PD Test was 10.45 U/gHb. The adjusted male median for the Pointe Scientific G6PD test run on Cobas Mira was 10.88 U/gHb.

The following tables summarize the agreement between the FINDER G6PD Test and the Pointe Scientific Glucose-6-Phosphate Dehydrogenase Reagent Set on Cobas Mira (on Cobas Mira) using different cutoffs. The results are presented as a percentage of the Adjusted Male Medium and include male, female, and contrived samples.

3 x 3 Contingency Table: <30% AMM, 30 to 70% AMM, ≥70% AMM

		Pointe Scientific Glucose-6-Phosphate Dehydrogenase Reagent Set on Cobas Mira			Total	Agreement	Wilson Score 95% CI	
		<30%	30 to 70%	> 70%				
FINDER G6PD Test	<30%	28	2	0	30	100.0%	87.9%	100.0%
	30 to 70%	0	22	2	24	68.8%	51.4%	82.1%
	> 70%	0	8	105	113	98.1%	93.4%	99.5%
	Total	28	32	107	167	92.8%	87.9%	95.8%

3 x 3 Contingency Table <30% AMM, 30 to 80% AMM, ≥80% AMM

		Pointe Scientific Glucose-6-Phosphate Dehydrogenase Reagent Set on Cobas Mira			Total	Agreement	Wilson Score 95% CI	
		<30%	30 to 80%	> 80%				
FINDER G6PD Test	<30%	28	2	0	30	100.0%	87.9%	100.0%
	30 to 80%	0	31	6	37	70.5%	55.8%	81.8%
	> 80%	0	11	89	100	93.7%	86.9%	97.1%
	Total	28	44	95	167	88.6%	82.9%	92.6%

2 x 2 Agreement Table <30% AMM, ≥30% AMM

		Pointe Scientific Glucose-6-Phosphate Dehydrogenase Reagent Set on Cobas Mira		Total	Agreement	Wilson Score 95% CI	
		<30%	≥30%				
FINDER G6PD Test	<30%	28	2	30	100.0%	87.9%	100.0%
	≥30%	0	137	137	98.6%	94.9%	99.6%
	Total	28	139	167	98.8%	95.7%	99.7%

2 x 2 Agreement Table <70% AMM, ≥70% AMM

		Pointe Scientific Glucose-6-Phosphate Dehydrogenase Reagent Set on Cobas Mira		Total	Agreement	Wilson Score 95% CI	
		<70%	≥70%				
FINDER G6PD Test	<70%	52	2	54	86.7%	75.8%	93.1%
	≥70%	8	105	113	98.1%	93.4%	99.5%
	Total	60	107	167	94.0%	89.3%	96.7%

2 x 2 Agreement Table <80% AMM, ≥80% AMM

		Pointe Scientific Glucose-6-Phosphate Dehydrogenase Reagent Set on Cobas Mira		Total	Agreement	Wilson Score 95% CI	
		<80%	≥80%				
FINDER G6PD Test	<80%	61	6	67	85.9%	76.0%	92.2%
	≥80%	10	90	100	93.8%	87.0%	97.1%
	Total	71	96	167	90.4%	85.0%	94.0%

9. Calibration Traceability

There is no international conventional reference measurement procedure or international conventional calibrator for G6PD. The G6PD assay on the Finder G6PD Cartridge is traceable to NADPH extinction coefficient of 6.3$mM^{-1}cm^{-1}$.

10. Quality Control

Performance of the FINDER system can be verified by analyzing hemolysate controls. Other controls may not be compatible.

11. Stability

The FINDER G6PD Test Cartridges are provided in sealed foil pouches. The expiration date of the unopened cartridge is stated on the outer label and is encoded in the barcode printed on the cartridge label. The current assigned shelf life is 77 weeks at 2–8°C from date of manufacturing.

12. Limitations of the Procedure

The FINDER G6PD test is indicated for lithium heparin venous whole blood samples.

G6PD levels may appear falsely elevated during or right after a severe hemolytic crisis because of higher G6PD levels in the new red cells[i]

Samples with low hemoglobin (<10.0 g/dL) on FINDER may result in clinically significant negative bias

Samples with high hemoglobin (>20.0 g/dL) on the FINDER can generate inaccurate results when a sample is not adequately mixed. Samples suspected of improper mixing should be retested using a new sample.

13. Conclusion

The results drawn from the non-clinical and clinical tests presented in these 510(k) submissions demonstrate that the FINDER G6PD test is safe, effective, and performs as well as the legally marketed predicate device identified in this 510(k) summary.

[i] E. Beutler, "G6PD Deficiency," *Blood,* vol. 84, no. 11, pp. 3613-3636, 1994.