DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 23, 2017

George King Bio-Medical, Inc.
Ms. Barbara Young
Director of Scientific Affairs
11771 W.112th Street
Overland Park, KS 66210

Re: K161316

Trade/Device Name: George King Coumadin® Plasma
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: January 20, 2017
Received: January 24, 2017

Dear Ms. Young:

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 addresshttp://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,

Leonthena R. Carrington -S

Lea Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161316

Device Name
George King Coumadin® Plasma

Indications for Use *(Describe)*
The George King Coumadin® Plasma is an assayed control plasma derived from a single donor on Coumadin® therapy and is intended for in vitro diagnostic use in monitoring the accuracy of the coagulation analyzer and thromboplastin using the clottable prothrombin time/INR on an optical instrument with appropriate commercial reagents. George King Coumadin® Plasma may be used when evaluating a new lot of thromboplastin reagent or new coagulation analyzer.

The intended users of the George King Coumadin® Plasma are trained laboratory personnel working in clinical laboratories.

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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GEORGE KING BIO-MEDICAL, INC.
Since 1973
SETTING THE PACE IN CLINICAL HEMATOLOGY

510(k) Summary (21 CFR 807.92)
Coumadin® Plasma

A. Submitter
George King Bio-Medical, Inc.
11771 W. 112th St
Overland Park, KS 66210
Telephone: (913) 469-5464
Fax: (913) 469-0871

B. Contact Person
Barbara Young
Director of Laboratory Operations
Telephone: (913) 469-5464
Fax: (913) 469-0871

C. Date prepared: 2-10-17

D. Device Identification

Common Name: Coumadin® Plasma
Product Trade Name: George King Coumadin® Plasma

Classification Regulation: Plasma, Coagulation

E. Substantial Equivalence Information

Predicate device name: CryoCheck INR Validation Set
Predicate 510(k) number: K971219
Precision BioLogic Inc.
140 Eileen Stubbs Ave, Dartmouth, NS B3B 0A9 Canada
Telephone: (902) 468-6482

F. Device Description

Each lot of George King Coumadin® Plasma is from a single human donor stabilized on at least 6-weeks of Coumadin® therapy. The donor plasma is obtained via plasmapheresis using 4.0% sodium citrate and frozen immediately at -70˚C.

The INR of the donor plasma is determined using the ACL Top 500 using RecombiPlastin 2G and each plasma is then categorized into one of the three INR levels of control material based on the testing results obtained using the following INR calculation:

$$INR = \left(\frac{\text{Patient PT}}{\text{Mean of normal range}} \right)^{ISI}$$

Level 1 - INR Control: 1.5-2.8
Level 2 - INR Control: 2.9-4.0
Level 3 - INR Control: >4.0

G. Intended Use

The George King Coumadin® Plasma is an assayed control plasma derived from a single donor on Coumadin® therapy and is intended for use in monitoring the accuracy and control of oral anticoagulant therapy using the INR on an optical instrument with appropriate commercial reagents.
The intended users of the George King Coumadin® Plasma are trained laboratory personnel working in clinical laboratories and research centers.

H. Technical Comparison with Predicate

Similarities

ITEM	DEVICE	PREDICATE
	George King Coumadin® Plasma	Precision BioLogic CryoCheck INR Validation Set (K971219)
Indications for use	The George King Coumadin® Plasma is an assayed control plasma derived from a single donor on Coumadin® therapy and is intended for in vitro diagnostic use in monitoring the accuracy of the coagulation analyzer and thromboplastin using the clottable prothrombin time/INR on an optical instrument with appropriate commercial reagents. George King Coumadin® Plasma may be used when evaluating a new lot of thromboplastin reagent or new coagulation analyzer. The intended users of the George King Coumadin® Plasma are trained laboratory personnel working in clinical laboratories.	The Prothrombin Time (PT) was first described by Quick and is a common method of monitoring oral anticoagulant treatment in patients receiving warfarin and related drugs. In 1983 the World Health Organization (WHO) described a scheme for PT standardization based on the Internal Normalized Ratio (INR). Indicated for use in monitoring the accuracy and control of oral anticoagulant therapy using the INR. Not intended for use as calibration or reference plasma and should not be used for calibrating the local International Sensitivity Index (ISI) of commercial thromboplastins. Designed to enhance the effective monitoring of oral anticoagulant therapy

ITEM	DEVICE	PREDICATE
	George King Coumadin® Plasma	Precision BioLogic CryoCheck INR Validation Set (K971219)
Product Code	GGN- Plasma, Coagulation Control	GGN- Plasma, Coagulation Control
Test Principle	INR= $\left(\frac{\text{Patient PT}}{\text{Mean of normal range}}\right)^{ISI}$	Same
Composition	Human fresh frozen citrated plasma with no additives	Assumed frozen citrated plasma since most controls sold by P.B are frozen in nature.

Differences

ITEM	DEVICE	PREDICATE
Preparation	Collected via plasmapheresis from individual human donors stabilized on Coumadin® therapy.	Well characterized warfarinized plasmas (could not find preparation method)
How Sold	Purchased by individual vials, not as a "set".	Packaged as a "set" with varying INR ranges

- **Has the same indications for use**
- **Same test principle and composition**
- **Demonstrates that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device.**

I. Summary of Performance Characteristics

1. Analytical performance

a. Precision

Precision was assessed in-house on 3 different lots of each of 3 INR ranges of GK Coumadin® Plasma on the ACL TOP 500. Precision was evaluated in accordance with CLSI EP05-A2, for 20 days with 2 runs per day and 2 replicates per run for each sample (n=80) using a specific lot of RecombiplasTin 2G.

INR Range: 1.5 – 2.8

Sample Description	Mean Value	n	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Lot 1	2.33	80	0.04 / 1.82		0.00 / 0.00		0.03 / 1.54		0.05 / 2.38	
Lot 2	2.27	80	0.03 / 1.75		0.00 / 0.00		0.03 / 1.30		0.02 / 1.30	
Lot 3	2.31	80	0.04 / 1.98		0.00 / 0.00		0.03 / 1.32		0.03 / 1.32	

Protime

Sample Description	Mean Value	n	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Lot 1	28.2	80	0.51 / 1.81		0.00 / 0.00		0.44 / 1.56		0.67 / 2.39	
Lot 2	27.5	80	0.48 / 1.76		0.00 / 0.00		0.36 / 1.33		0.61 / 2.21	
Lot 3	27.9	80	0.55 / 1.98		0.00 / 0.00		0.37 / 1.34		0.67 / 2.39	

INR Range: 2.9 – 4.0

Sample Description	Mean Value	n	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Lot 1	3.25	80	0.04 / 1.53		0.00 / 0.00		0.04 / 1.39		0.06 / 2.07	
Lot 2	3.03	80	0.04 / 1.53		0.00 / 0.00		0.03 / 1.17		0.05 / 1.93	
Lot 3	2.83	80	0.03 / 1.28		0.00 / 0.00		0.03 / 1.05		0.04 / 1.66	

Protime

Sample Description	Mean Value	n	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Lot 1	39.3	80	0.61 / 1.55		0.00 / 0.00		0.56 / 1.41		0.83 / 2.10	
Lot 2	36.9	80	0.58 / 1.57		0.00 / 0.00		0.44 / 1.19		0.73 / 1.97	
Lot 3	34.5	80	0.45 / 1.32		0.00 / 0.00		0.37 / 1.08		0.59 / 1.70	

INR Range: > 4.1

Sample Description	Mean Value	n	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Lot 1	4.66	80	0.05 / 1.14		0.00 / 0.00		0.04 / 1.03		0.07 / 1.54	
Lot 2	6.95	80	0.10 / 1.46		0.00 / 0.00		0.05 / 0.79		0.11 / 1.66	
Lot 3	4.74	80	0.06 / 1.45		0.00 / 0.00		0.03 / 0.75		0.07 / 1.64	

Protime

Sample Description	Mean Value	n	Within-Run		Between-Run		Between-Day		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Lot 1	57.2	80	0.66 / 1.16		0.00 / 0.00		0.61 / 1.07		0.90 / 1.58	
Lot 2	86.0	80	1.28 / 1.49		0.00 / 0.00		0.69 / 0.80		1.46 / 1.69	
Lot 3	58.3	80	0.85 / 1.46		0.00 / 0.00		0.44 / 0.76		0.96 / 1.64	

- The results met pre-specified acceptance criteria of CV < 10%

b. Reproducibility

A reproducibility study was performed at three (3) different clinical laboratories, all using an ACL TOP series instruments and RecombiplasTin 2G (Site 1: ACL TOP 500, Site 2: ACL TOP 700, Site 3: ACL TOP 500) and multiple operators. Samples from each lot were assayed for 5 days, one run per day ,for a total of (N=75)

The tables below include the between site data for the reproducibility site evaluation. INR values are followed by the Protime values for each lot number.

INR Range: 1.5 – 2.8

Lot	Mean	n	Repeatability		Between Day		Between Site		Reproducibility	
			SD	CV	SD	CV	SD	CV	SD	CV
3603	2.32	75	0.02	0.85	0.05	2.44	0.02	0.92	0.06	2.74
3747	2.27	75	0.02	1.07	0.06	2.69	0.00	0.00	0.06	2.90
3746	2.30	75	0.03	1.40	0.06	2.81	0.00	0.00	0.07	3.14

Protime

Lot	Mean	n	Repeatability		Between Day		Between Site		Reproducibility	
			SD	CV	SD	CV	SD	CV	SD	CV
3630	27.9	75	0.24	0.86	0.70	2.51	0.12	0.44	0.75	2.70
3747	27.3	75	0.30	1.10	0.76	2.79	0.00	0.00	0.82	3.01
3746	27.6	75	0.39	1.41	0.81	2.92	0.00	0.00	0.89	3.24

INR Range: 2.9-4.0

Lot	Mean	n	Repeatability SD	Repeatability CV	Between Day SD	Between Day CV	Between Site SD	Between Site CV	Reproducibility SD	Reproducibility CV
3748	3.27	75	0.03	1.14	0.12	3.83	0.00	0.00	0.13	3.99
3749	3.06	75	0.09	3.18	0.08	2.63	0.00	0.00	0.12	4.13
3751	2.86	75	0.04	1.38	0.05	1.98	0.00	0.05	0.06	2.41

Protime

Lot	Mean	n	Repeatability SD	Repeatability CV	Between Day SD	Between Day CV	Between Site SD	Between Site CV	Reproducibility SD	Reproducibility CV
3748	39.7	75	0.46	1.17	1.54	3.90	0.00	0.00	1.61	4.07
3749	37.0	75	1.21	3.27	0.99	2.68	0.00	0.00	1.56	4.23
3751	34.6	75	0.48	1.39	0.70	2.04	0.00	0.00	0.85	2.47

INR Range: >4.0

Lot	Mean	n	Repeatability SD	Repeatability CV	Between Day SD	Between Day CV	Between Site SD	Between Site CV	Reproducibility SD	Reproducibility CV
3750	4.66	75	0.04	0.97	0.11	2.50	0.00	0.00	0.12	2.68
3752	6.94	75	0.08	1.16	0.28	4.09	0.00	0.00	0.29	4.26
3753	4.74	75	0.05	1.10	0.16	3.44	0.00	0.00	0.17	3.61

Protime

Lot	Mean	n	Repeatability SD	Repeatability CV	Between Day SD	Between Day CV	Between Site SD	Between Site CV	Reproducibility SD	Reproducibility CV
3750	56.9	75	0.55	0.98	1.45	2.55	0.00	0.00	1.56	2.73
3752	85.2	75	0.97	1.14	3.49	4.10	0.52	0.61	3.66	4.30
3755	57.9	75	0.63	1.10	2.04	3.52	0.00	0.00	2.13	3.68

- The results met pre-specified acceptance criteria of CV < 1

c. Stability Studies

Open Vial Stability Study: The open vial stability study was conducted on-board the ACL TOP instrument using three lots of GK Coumadin® plasma. The study demonstrated the GK Coumadin® Plasma is stable for 6 hours at 19-22˚C. The study met the pre-determined acceptance criteria.

Shelf-Life Stability Study: The closed vial stability study is being conducted at the storage temperature of -70˚C using three lots of GK Coumadin® plasma. The current stability claim is 6 months from the date of manufacture. Real time stability testing is on-going and will be used to update the shelf life as more data becomes available.

d. Interference Study: Not applicable

e. Detection limit: Not applicable

f. Analytical Specificity: Not applicable

g. Assay cut-off: Not applicable

2. Comparison Studies:

a. Method comparison with predicate device - Not applicable
b. Matrix comparison – Not applicable

3. Clinical Studies

a. Clinical Sensitivity – Not Applicable
b. Clinical Specificity – Not Applicable

4. Clinical Cut-off – Not applicable

5. Expected Values – A lot specific Certificate of Analysis with an assigned reference value is provided in the package insert accompanying the product.

J. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

K. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.