DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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MAGELLAN DIAGNOSTICS
REBA DAOUST
QA/RA MANAGER
101 BILLERICA AVE. BLDG #4
NORTH BILLERICA MA 01862

July 7, 2015

Re: K142705
Trade/Device Name: LeadCare® Plus™ Blood Lead Testing System
Regulation Number: 21 CFR 862.3550
Regulation Name: Lead test system
Regulatory Class: II
Product Code: DOF
Dated: June 26, 2015
Received: June 29, 2015

Dear Reba Daoust:

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 regulations (21 CFR Parts 801 and 809), 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" (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.

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,

Katherine Serrano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142705

Device Name
LeadCare® Plus™ Blood Lead Testing System

Indications for Use *(Describe)*
The LeadCare® Plus™ Blood Lead Testing System is intended for the quantitative measurement of lead in a whole blood sample. The LeadCare Plus Blood Lead Testing System is intended for in vitro (external) use only. The test kit components are for use with both the LeadCare Plus and LeadCare Ultra® Blood Lead Testing Systems.

This test system is for prescription use only. This system is not intended for point of care use.

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

Applicant Contact Information:

Applicant:	Magellan Diagnostics
Address:	101 Billerica Ave., Building 4 N. Billerica, MA, 01862-1272
Contact Person:	Reba Daoust Director of QA/RA
Phone Number:	978-248-7811
Fax Number:	978-856-2335
E-mail:	rdaoust@magellandx.com

Device Trade Name: LeadCare® Plus™

Regulatory section:	21 CFR 862.3550
Classification:	Class II
Product Code:	DOF
Panel:	Toxicology

Date Summary Prepared: 06/26/2015

Indications for Use:

The LeadCare® Plus™ Blood Lead Testing System is intended for the quantitative measurement of lead in a whole blood sample. The LeadCare Plus Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are for use with both the LeadCare Plus and LeadCare Ultra® Blood Lead Testing Systems.

This test system is for prescription use only. This system is not intended for point of care use.

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Device Description and Test Principle:

The LeadCare Plus Blood Lead Testing System is a new instrument to the LeadCare line of instruments. The predicate, LeadCare Ultra, is a 6-channel analyzer which has the same intended use as the LeadCare Plus. The LeadCare Plus instrument is a one-channel version of this system. The LeadCare Plus Analyzer is used in conjunction with the same test kit components, including: sensors, control materials, and single-use packaged reagent tubes as utilized with the predicate device, LeadCare Ultra. The single-channel LeadCare Plus analyzer is an *in vitro* diagnostic device that relies on electrochemistry (Anodic Stripping Voltammetry or ASV).

The analyzer is a low voltage potentiostat that runs on AC power or batteries and has dimensions of 9”x6.5”x3.5”. It is equipped with a Liquid Crystal Display (LCD) Screen, Sensor Connector and Calibration Button reader. The Screen displays instructions for the blood lead assay, result, lot code and error messages. The Calibration Button reader allows for the download of all calibration information, analytical test parameters, and lot code information for any given Sensor lot.

For measurement of lead, the whole blood sample is pipetted to a packaged reagent tube. Upon mixing, the red blood cells are ruptured and the lead is released from the proteins and becomes labile and available for electrochemical detection. After the sample mixture is applied to the sensor, the analyzer applies an electrical potential that causes the lead to reduce (collect) on the sensor. After three minutes, the analyzer applies potentials that cause the lead to oxidize back into solution. The current produced is measured and the amount of lead in the sample is calculated. The analytical result is displayed on the screen in micrograms per deciliter (µg/dL).

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Predicate Device:

K123563 LeadCare Ultra®

Substantial Equivalence Information:

The LeadCare Plus Blood Lead Testing System is a single channel version of the predicate device, LeadCare Ultra Blood Lead Testing System, 510(k) K123563. The following table summarizes the similarities and differences between the two devices.

Feature	LeadCare Ultra - Predicate	LeadCare Plus
Intended Use	The LeadCare Ultra® Blood Lead Testing System is designed to quantitatively measure the amount of lead in a whole blood sample. The LeadCare Ultra Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are designed for use only with the LeadCare Ultra Blood Lead Testing System. This test system is for prescription use only. This system is not intended for point of care use.	The LeadCare® Plus™ Blood Lead Testing System is intended for the quantitative measurement of lead in a whole blood sample. The LeadCare Plus Blood Lead Testing System is intended for *in vitro* (external) use only. The test kit components are for use with both the LeadCare Plus and LeadCare Ultra Blood Lead Testing Systems. This test system is for prescription use only. This system is not intended for point of care use.
Methodology	Anodic Stripping Voltammetry	Same
Throughput	6 samples at a time	1 sample at a time
Sensor (test strip)	Screen printed sensors with conductive inks; plastic spacer and lid; capillary fill	Same
Active Test Electrode area	Thin layer of colloidal gold in an inert polymer matrix	Same
Calibration	Electronic calibration button	Same
Blood Collection	Fingerstick or venipuncture	Same
Sample Matrix	Whole blood; up to 72 hours from time of draw	Same
Treatment Reagent	Dilute hydrochloric acid in water with inert carbon particles	Same
Sample Handling	Uses pipet to transfer sample from reagent tube to sensor	Same
Check for Sensor Lot Expiration	Checks sensor lot expiration date	Same
Internal Self Test	Self Test checks electronic functions of analyzer each time it is turned ON and on each channel following a sensor insertion	Self Test checks electronic functions every time the analyzer is turned ON
Sensor Connector	Makes electrical contact with sensor. Sensor insertion detection.	Same

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Feature	LeadCare Ultra - Predicate	LeadCare Plus
Unit of Measure	Results displayed in micrograms of lead per deciliter of whole blood (μg/dL)	Same
Displayed Result	Lead results stored in computer	Lead result is displayed until new sensor is inserted
Reportable Range	1.9 – 65 μg/dL	Same
Controls	2 levels of external liquid controls	Same
Power Source	AC Adapter or batteries	Same
Test Time	3 minutes	Same
Software	Software is in the form of firmware installed onto the analyzer's microprocessor User Interface software, installed on the computer workstation, displays results and provides Data Management capability	Software is in the form of firmware only, installed onto the analyzer's microprocessor Results displayed on LCD screen
Lead Test Algorithm	ASV routine; Pb peak identified and quantified; blood Pb result assigned using lookup tables	Same
Storage of Results	Computer stores the patient results and allows for retrieval of stored results	None
Output of Results	Results displayed on screen. Results can be printed and transferred to a LIMS accessible location	Result displayed on screen
Audible Tones	Beep at power up; at beginning of test; at end of test; after calibration	Same
User Interface	Graphical user interface with messages and graphics to guide users through procedure	Alphanumeric display, 4 lines by 20 characters allows useful messages to guide users through procedure
System Operating Range	Temperature range of 16° to 30°C; (60.8° to 86°F); Relative Humidity 12%-80% non-condensing to accommodate typical laboratory use	Same
Limit of Detection	1.9 μg/dL	Same
Numeric Resolution (Result)	0.1 μg/dL	Same

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Summary of Non-Clinical and Clinical Performance Testing as Basis for Substantial Equivalence:

A. Non-Clinical Results

Precision

The Precision Study was performed using bovine blood standards at lead concentrations of 3.1, 5.1, 11.7, 24.7 and 45.4 µg/dL. An additional human blood sample at lead concentration of 59.1 µg/dL was also included to challenge the high end of the range. Eighty (80) data points were collected per concentration level over a 20 day period using two Sensor/Reagent Lot Pairs following CLSI EP05-A2 guidelines. Samples were prepped two times per day. The LeadCare Plus precision passed the pre-defined acceptance criteria.

The combined data set is shown: Summarized ANOVA Results for Both Sensor/Reagent Lot Pairs

Mean, µg/dL	WR* SD, µg/dL	Total SD, µg/dL	WR CV	Total CV
3.1	0.44	0.49	14.1%	15.6%
5.1	0.44	0.50	8.5%	9.6%
11.7	0.64	0.71	5.3%	6.0%
24.7	0.80	1.00	3.2%	4.0%
45.4	1.61	1.71	3.5%	3.7%
59.1	1.89	2.42	3.2%	4.0%

*WR = within run

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Linearity

Linearity assessments were performed on two Sensor/Reagent Lot Pairs using nine donor blood samples, spiked with lead to concentrations of 0-2 µg/dL, 2-5 µg/dL, 5-10 µg/dL, 15-25 µg/dL, 25-35 µg/dL, 35-45 µg/dL, 45-55 µg/dL, 55-65, 65-70 µg/dL. One whole blood, unadulterated in K_2EDTA vacutainers, was also included.

Linearity was evaluated by performing polynomial regressions and determining whether higher order coefficients were statistically significant as per CLSI EP06-A Section 5.32.

The Linear Regression results for each of the two Sensor/Reagent Lot Pairs are as follows:

1312B/021214U	1310A/041014U
$Y = 1.11x - 1.49$	$Y = 1.08x - 0.803$
$R^2 = 0.998$	$R^2 = 0.997$

Limit of Blank, Limit of Detection & Limit of Quantification

The Limits of Blank, Detection and Quantification were established using the Total Error Analysis Method and by following the CLSI EP17-A2 guidelines.

The Limit of Blank (LoB) was determined by running 60 replicates of near blank bovine blood samples, over 5 days. Samples were analyzed using two Sensor/Reagent Lot Pairs.

The average LoB was calculated to be 0.98 µg/dL.

The Limit of Detection (LoD) and Limit of Quantification (LoQ) were determined by running 60 replicates of 10 different whole blood samples, collected in K_2EDTA vacutainers. The replicates were run, using two Sensor/Reagent Lot Pairs on LeadCare Plus analyzers over five days.

The average LoD was calculated to be 1.2 µg/dL.

The Limit of Quantification LoQ was calculated using the Total Error equation:

Total Error LoQ = absolute (Bias) + (2 x SD)

The average LoQ was calculated to be 1.6 µg/dL.

The Total Error at the LoQ was 18%.

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Obtained LoB, LoD, and LoQ values for the LeadCare Plus differ slightly from those obtained for the LeadCare Ultra (See k123563). For product family consistency between LeadCare Plus and LeadCare Ultra, the claimed values for LoB, LoD and LoQ of the LeadCare Plus are provided in the table below and are identical to the values obtained for the LeadCare Ultra:

	LeadCare Plus
LoB	1.5 µg/dL
LoD	1.9 µg/dL
LoQ	1.9 µg/dL

Interference

See k123563 for interference information.

B. Clinical Results

Method Comparison

The Method Comparison Study was conducted at one site with two Sensor/Reagent Lot Pairs; two labs; two users and two stations of six LeadCare Plus analyzers. To determine accuracy, based on CLSI EP09-A3, clinical samples were run on the LeadCare Plus systems and the results were compared to the predicate method, LeadCare Ultra and to the reference method, Graphite Furnace Atomic Absorption Spectroscopy (GFAAS).

Whole blood samples collected in K_2EDTA Vacutainers, were run singly on the LeadCare Plus and predicate device, LeadCare Ultra; and in duplicate on the reference method, GFAAS. Two hundred eighty four (284) results were generated and 169 were within range of 1.9 - 65 µg/dL.

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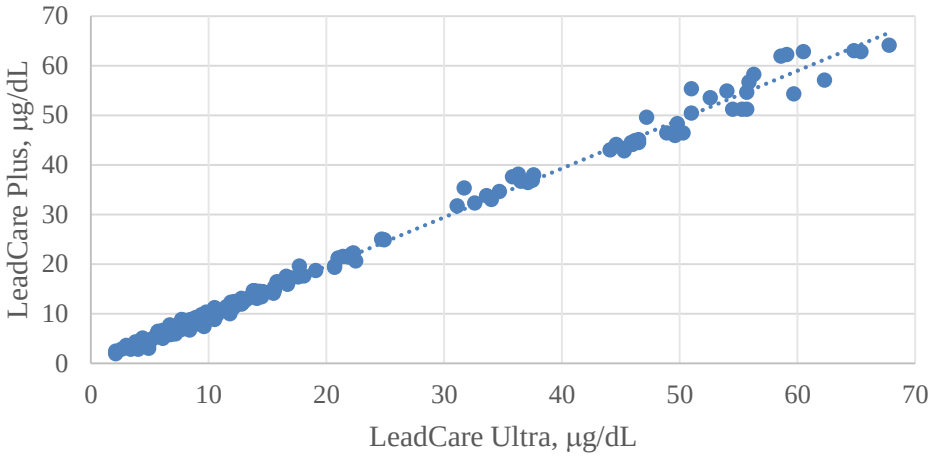
The linear regression analysis for LeadCare Plus vs. LeadCare Ultra is shown below:

Slope	Intercept	R^2	N
0.985	-0.10	0.994	169

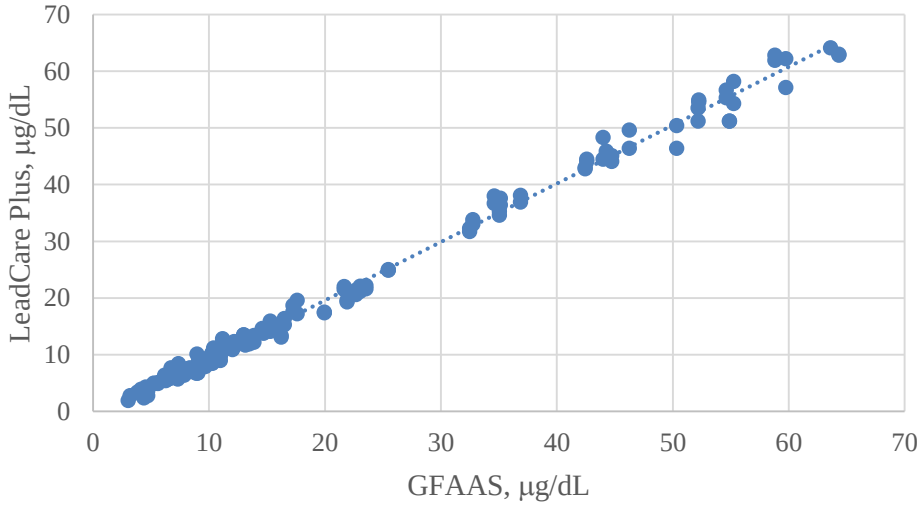
A graph of the actual LeadCare Plus Results vs. LeadCare Ultra is as follows:



The Linear Regression Results of LeadCare Plus vs. GFAAS is shown below:

Slope	Intercept	R^2	N
1.029	-0.98	0.994	169

A graph of the actual LeadCare Plus results vs. GFAAS is shown below:



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Matrix Comparison

Matrix Comparisons were made for the Micro-capillary tubes with K_2EDTA. The bloods had lead concentrations that spanned the range 1.9 to 63.1 µg/dL, based on GFAAS. Twenty three results were obtained from native patient samples. Twenty seven results were obtained with contrived blood samples, spiked with lead.

The Linear Regression Results of LeadCare Plus vs. GFAAS is shown below:

Slope	Intercept	R^2	Concentration Range, µg/dL	N
1.018	0.023	0.983	1.9 - 63.1	50

See k123563 for other Matrix Comparison results using:

- K_3EDTA, K_2EDTA Vacutainers
- Sodium Heparin Vacutainers

Conclusions:

The LeadCare Plus System is substantially equivalent to the previously cleared predicate product. The proposed device raises no new issues of safety and effectiveness. The non-clinical and clinical testing summarized demonstrates that the LeadCare Plus met all the specifications and is suitable for its intended use.

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