OCT 6 - 2005

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**510(k) summary of safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.**

**The assigned 510(k) number is:** K052549


**ESA BIOSCIENCES, INC.**
**ESA INTERNATIONAL, INC.**

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**CYPRESS SYSTEMS**

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1. Submitter's Information

   ESA Biosciences Inc
   22 Alpha Road
   Chelmsford, MA 01824 USA

   Contact: Harold Asp, Quality Assurance Manager
   Phone: (978) 250-7000
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   Date Summary Prepared: September 15, 2005

2. Device Name

   Product Name: LeadCare® II Blood Lead Testing System
   Classification Name: Atomic Absorption, Lead
   Common/Usual Name: Anodic Stripping Voltammetry (ASV)
   Proprietary Name: LeadCare® II Blood Lead Testing System
   Product Code: DOF

3. Predicate Device

   Substantial Equivalence to ESA Bioscience Inc. (formerly ESA Inc.) LeadCare® Blood Lead Testing System. (K971640)

4. Device Description

   The LeadCare® II Blood Lead Testing System is an instrumented assay utilizing electrochemistry and a unique sensor to be used for the quantitation of lead in whole human blood. Testing can be performed on venous or capillary samples. The system is comprised of an analyzer, sensor (single use, disposable), reagent vial (filled with a measured amount of Treatment Reagent) and a calibration button. The system is powered by 4 AA batteries or AC Adapter. A built in self test checks the electronic functions of the analyzer each time it is turned on. Blood lead controls are available to monitor the precision and accuracy of the system.

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The methodology of the system is Anodic Stripping Voltammetry (ASV). Most lead is carried in red blood cells. When a sample of whole blood is mixed with Treatment Reagent, the lead in the red blood cells is released and made available for detection. During the Pb test, the analyzer causes the lead to collect on the sensor. After a specified time, the analyzer removes the lead accumulated on the sensor. The current response (a peak shaped curve) is baseline corrected, quantified and converted to a blood Pb value. The analyzer displays the blood Pb level in units of µg/dL.

The test electrode is covered by a thin layer of colloidal gold in an inert polymer matrix. The treatment reagent contains a dilute hydrochloric acid solution in water.

5. Intended Use

The LeadCare® II Blood Lead Testing System is an instrumented assay to be used in the quantitation of lead in whole human blood. The LeadCare® II System is suitable for use in a physician's office laboratory (POL).

6. Comparison to Predicate Device

The LeadCare® II Bllod Lead Testing System is a modification of the LeadCare® Blood Lead Testing System and is substantially equivalent to it. The table below summarizes the similarities and differences.

| Feature | LeadCare® System | LeadCare® II System |
|---|---|---|
| Intended Use | An Instrumented assay to be Used in the quantitation of Lead in human whole blood. The LeadCare®System is suitable for use in Physician's Office Laboratory Environment (POL) | Same as LeadCare®. |
| Methodology | Anodic Stripping Voltmmetry (ASV) | Same as LeadCare®. |
| Sample Matrix | Fresh human whole blood | Same as LeadCare®. |
| Blood Collection | Skin puncture or venipuncture | Same as LeadCare®. |
| Treatment Reagent | Dilute hydrochloric acid solution in water | Same as LeadCare®. |
| Sample handling | Uses 50µl pipette to transfer sample from reagent tube to sensor | Uses 50µl capillary tube to transfer sample from reagent tube to sensor |

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| Feature | LeadCare® System | LeadCare® II System |
|---|---|---|
| Sensor (Test Strip) | (2)Screen printed conductive inks on an inert polymer substrate. (1) screen printed dielectric ink is for insulation and electrode area definition. | Same as LeadCare®. In addition, a plastic spacer and lid are attached to the sensors to create a channel, which fills via capillary action. |
| Active Test Electrode area | Test electrode is covered by a thin layer of colloidal gold in an inert polymer matrix | Same as LeadCare®. |
| Calibration | Electronic calibration button | Same as LeadCare®. |
| Check for Sensor Lot Expiration | None | Checks sensor lot expiration date passed in on the calibration button for that particular lot of sensors. |
| Internal Self Test | Self test checks electronic functions of analyzer each time it is turned on | Same as LeadCare®. |
| Sensor Connector | Makes electrical contact with sensor. | Sensor insertion detection and makes electrical contact with sensor. |
| Unit of Measure | Results displayed in micrograms of lead per deciliter of whole blood (µg/dl of Pb) | Same as LeadCare®. |
| Displayed Result | Pb result is displayed until the Start button is pressed. Upon power-up after auto shut-off, last result is displayed. | Pb result is displayed until a new sensor is inserted. |
| Reportable Range | 1.4 –65 µg/dl of Pb | Same as LeadCare®. |
| Controls | 2 levels of external control | 2 levels of external control |
| Power Source | AC Adapter or one 9 volt battery | AC Adapter or 4 AA batteries |
| On/Off | Start button acts as On switch; auto shut-off | On/Off switch and auto shut-off |
| Test Time | 3 minutes | Same as LeadCare®. |
| Initiation of Test | User presses Start button after applying sample. | Analyzer starts the test after confirming enough sample has been added to the sensor. |
| Pb Test Algorithm | ASV routine; Pb peak identified and quantified; blood Pb result assigned using look-up tables | Same as LeadCare®. |
| Error Messages | 5 error codes | 16 error messages |
| Audible Tones | "Beep" at power-up; at beginning of test; at end of test; after calibration. | Same as LeadCare®. |
| User Interface | Custom display, limited message capability | Alphanumeric display, 4 lines by 20 characters allows useful messages to guide users through procedure |

| Feature | LeadCare® System | LeadCare® II System |
|---|---|---|
| System Operating Range | Temperature: 54°-97° F (12-36°C) Relative Humidity 12%-80% (non condensing) | Same as LeadCare®. |
| Sensitivity (Limit Of Detection) | 1.4 µg/dl Pb | 1.5 µg/dl Pb |
| Display Resolution | 0.1 µg/dl Pb | Same as LeadCare®. |

7. Discussion of Non-Clinical Performance Data

A method comparison study was conducted in which 108 human samples were run on six LeadCare II analyzers over 5 days and compared with results run by graphite furnace atomic absorption spectroscopy (GFAAS). Of the 108 samples, 22 were spiked (86 were unspiked).

The results from this study gave the following regression:

Y (LeadCare II) = 1.040 x GFAAS + 0.12, $s_{y.x}$ =1.30 , r = 0.996

The average LeadCare II bias from reference is shown in Table 1 for three ranges.

**Table 1**
**Average LeadCare II average bias from GFAAS**

| Lead concentration µg/dL | LeadCare II bias from GFAAS | LeadCare II % bias from GFAAS |
|---|---|---|
| 0 – 10 | 0.07 | ----- |
| 10.1 – 25.0 | ----- | 4.7% |
| 25.1 - 65 | ----- | 5.0% |

These results are similar to the LeadCare results, which had a regression equation of:

Y (LeadCare I) = 0.992 x GFAAS + 0.94

Since the LeadCare II average biases are well within goals, LeadCare II is substantially equivalent to LeadCare .

8. Conclusions

In summary, based on comparison with the legally marketed LeadCare® Blood Lead Testing System, the data demonstrates that the LeadCare® II Blood Lead testing System performs as well as the predicate device and do not present new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 6 - 2005

Mr. Harold Asp
Quality Assurance Manager
ESA Biosciences Inc.
22 Alpha Road
Chelmsford, MA 01824

Re: k052549
Trade/Device Name: LeadCare® II Blood Lead Testing System
Regulation Number: 21 CFR 862.3550
Regulation Name: Lead test system
Regulatory Class: Class II
Product Code: DOF
Dated: September 15, 2005
Received: September 16, 2005

Dear Mr. Asp:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K052549

Device Name: LEADCARE® II BLOOD LEAD TESTING SYSTEM

Indications For Use:

**For In Vitro Diagnostic Use Only**

The LeadCare® II Blood Lead Testing System is an instrumented assay to be used in the quantitation of lead in human whole blood. The Leadcare® II System is suitable for use in a physician's office laboratory environment (POL).

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Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052549