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

January 17, 2017

Immunostics, Inc.
Antoinette Prusik
Director Regulatory Affairs
1750 Brielle Ave. Suite A5
Ocean, New Jersey 07712

Re: K163554
Trade/Device Name: hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: KHE
Dated: December 15, 2016
Received: December 19, 2016

Dear Ms. Prusik:

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 Part 801); 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 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,

Leonthena R. Carrington -S

Leonthena R. 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)*
K163554

Device Name
hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test

Indications for Use *(Describe)*
hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test is a rapid, convenient, and non-offensive qualitative method for detecting occult blood in the stool. It is intended for professional use as an aid in the diagnosis of asymptomatic gastrointestinal conditions that may manifest themselves by the presence of occult blood in the stool. This test is recommended for use in routine hospital testing, mass screening programs for colorectal cancer, and in testing of postoperative patients and newborn infants.

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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Special 510(k) Summary

hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR, Section 807.92.

Date Summary prepared: December 15th 2016

Regulatory Correspondent

Immunostics, Inc.
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Fax No.: (732) 918-0618
Contact: Antoinette Prusik
E-mail: aprusik@immunostics.com
Website: www.immunostics.com
Establishment Registration Number: 2244821

Device Information

Trade Name: hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test
Common Name: Reagent, Occult Blood
Regulation Name: Occult Blood Test
Product Code: KHE

Regulation: 21 CFR § 864.6550

Predicate Device: hema-screen™ ER
Predicate 510(k) Number: K102664

Intended Use/Indications for Use(s):

hema-screen ER XCEL™ is a rapid, convenient, and non-offensive qualitative method for detecting occult blood in the stool. It is intended for professional use as an aid in the diagnosis of asymptomatic gastrointestinal conditions that may manifest themselves by the presence of occult blood in the stool. This test is recommended for use in routine hospital testing, mass screening programs for colorectal cancer, and in testing of postoperative patients and newborn infants.

Device Description: Subject Device

hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test

Principles of Test

hema-screen ER XCEL™ in its original concept as slides and tape was designed to offer the hospital, mass screening programs and clinical laboratories a convenient rapid method for handling fecal specimens in testing for occult blood. **hema-screen ER XCEL™** is especially useful for mass screening programs as its enhanced readability feature facilitates the technicians' ability to make a determination.

hema-screen ER XCEL™ eliminates the mess and odors associated with the collection and transport of fecal specimens. Slides can be prepared at the patient's bedside and placed in a sealed envelope or by the patient at home and mailed to the hospital or laboratory in an inoffensive manner for development and evaluation.

hema-screen ER XCEL™ single slides are convenient for use when single stool specimens are to be tested. A single test is indicated when blood loss in the gastrointestinal tract is strongly suspected, for example, in persons with symptoms of ulcers, anemia, black stools or postoperative patients.

hema-screen ER XCEL™ Enhanced Readability Patient Packs are to be utilized so the patient can serially collect specimens at home over the course of three bowel movements. Patients should be instructed to follow the directions exactly, as the potential for false positive results exists due to improper diet, blood on the hands, hemorrhoids or if the test is used during menstrual bleeding. After all three slides are prepared, the slides may be sent back to the hospital laboratory for developing and evaluation. Preparation of three consecutive slides is recommended for screening asymptomatic patients by the American Cancer Society.

When stool specimens containing occult blood are applied **hema-screen ER XCEL™** test paper, the hemoglobin portion of the occult blood comes in contact with the guaiac. When the **hema-screen ER XCEL™** peroxide developing solution is added, a guaiac-peroxidase like reaction occurs. The chemical reaction becomes visible by the appearance of a blue-green color between 30 seconds and 60 seconds if occur blood is present.

Substantial Equivalence Information

Characteristic	Proposed Device **hema-screen ER XCEL™** **Enhanced Readability**	Predicate Device **K102664** **hema-screen™ ER**
Intended Use/Indications for Use	**hema-screen ER XCEL™** is a rapid, convenient, and non-offensive qualitative method for detecting occult blood in the stool. It is intended for professional use as an aid in the diagnosis of asymptomatic gastrointestinal conditions that may manifest themselves by the presence of occult blood in the stool. This test is recommended for use in routine hospital testing, mass screening programs for colorectal cancer, and in testing of postoperative patients and newborn infants.	**Same**
Materials Provided	**hema-screen ER XCEL™** Slides -A special electrophoresis paper impregnated with natural guaiac resin. Contains both positive (+) and negative (-) performance standards. The positive (+) standard contains a hemoglobin derived catalyst on the slide. **hema-screen ER XCEL™** Developing Solution (enhanced) – Contains a stabilized mixture of hydrogen peroxide (less than 6%) and (75% denatured ethyl alcohol with additives in aqueous solution. **hema-screen ER XCEL™** Laboratory Pack – Instructions for use, 100 single slides with Performance Standards, two (2)	**Same** **Same** **Same**

	10 ml bottles of Developing Solution, and 100 applicator sticks. Also available in 50 pack.	

Technological Characteristics:

The fundamental scientific technology of the modified device has not changed. The change is for the addition of an *optional* patient sampling slide with GRID: the internal guaiac paper has neither been modified nor reformulated; the outer cardboard contains smaller surface area (small circles) to help prevent oversampling and ease of use for the patient.

There is no change in analytical sensitivity of the new device.

The intended use/indication use of the modified device as described in the labeling has not changed**.**

Name change to **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test**. Both patient sampling slide versions (GRID and Non-GRID) are available and optional in **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test**.

Substantial Equivalence:

Similarities

Subject Device	**Predicate Device K102664**
Intended Use	Intended Use
Operating Principal	Operating Principal
Materials	Materials
Basic Design	Basic Design
Shelf Life	Shelf Life
Enhanced Developing Solution	Enhanced Developing Solution

Differences

Item	**Subject Device hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test**	**Predicate hema-screen™ ER K102664**
Design	Both patient sampling slide versions (GRID and non-GRID) are available and optional.	Only the non-GRID version
Materials Provided	hema-screen ER XCEL™ Patient Pack – Instructions for use, 50	hema-screen™ ER Patient Pack – Instructions for use, 150 patient

Item	Subject Device hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test	Predicate hema-screen™ ER K102664
	patient slides with a GRID design for easy readability. Performance Standards, three 10mL bottles of Developing Solution, 150 applicator sticks, patient instructions and 50 foil-lined mailing pouches.	slides without a GRID with Performance Standards, three 10mL bottles of Developing Solution, 150 applicator sticks, patient instructions and 50 foil-lined mailing pouches.

Design Control Activities Conducted:

A Risk Analysis was used to assess the impact of the modifications on the device and its components, and the results of the analysis.
Based on the Risk Analysis, an identification of the verification and/or validation required, including methods or tests used and acceptance criteria was applied and found to be satisfactory.
A Declaration of Conformity statement with design controls is presented.

Conclusion Drawn:

The **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test** is as safe and effective as the predicate device, **hema-screen™ ER.**
The **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test** has the same intended use and indications for use and fundamental scientific technology.
The difference between the subject device, **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test** and predicate device, **hema-screen™ ER** (addition of an *optional* GRID design version of the **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test)** raises no new issues of safety and effectiveness.
The **hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test** is substantially equivalent to the predicate device.