DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 13, 2017

ENTERIX INC.
c/o RONALD SCHOENGOLD
PRINCIPAL
19000 SARATOGA GLEN PLACE
SARATOGA, CA 95070

Re: K170548
Trade/Device Name: InSure® ONE™ – One Day Fecal Immunochemical Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: KHE
Dated: August 28, 2017
Received: September 5, 2017

Dear Mr. Schoengold:

This letter corrects our substantially equivalent letter of October 5, 2017.

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 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" (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
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)* K170548

Device Name

InSure® ONE™ One Day Fecal Immunochemical Test

Indications for Use *(Describe)*

Intended Use/Indications for Use

The InSure® ONE™ is a fecal immunochemical test (FIT) that qualitatively detects human hemoglobin from blood in fecal samples. The samples will generally be collected by the test subject at home and the test developed at laboratories or professional offices. The InSure® ONE™ test is used to aid in the detection of lower gastrointestinal bleeding.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) InSure® ONE™ Developer Kit Components

☒ Over-The-Counter Use (21 CFR 801 Subpart C) InSure® ONE™ Sample Collection Kit

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(As required by 21CFR 807.92)

Submitter
Enterix Inc., A Clinical Genomics Inc. Company
236 Fernwood Avenue
Edison, NJ 08837, USA
732 429 1899

Contact Person
Michele Houldsworth, Vice President Regulatory Affairs

Date of Preparation
September 30, 2017

Device Name
InSure® ONE™
One Day Fecal Immunochemical Test

Common Name
Fecal Occult Blood Test

Classification Name
Fecal Immunochemical Test

Regulation Number
21 CFR 864.6550

Product Code
KHE

Predicate Devices
InSure® FIT™ (Fecal Immunochemical Test)

Device Description

The InSure® ONE™ – One Day Fecal Immunochemical Test qualitatively detects human hemoglobin from blood in fecal samples. The fecal sample is generally collected by the test subject at home. Toilet bowl water samples are taken using long handled brushes to collect a small volume of water from around the defecated stool. The toilet water test sample once collected is placed on an InSure ONE Test Card. The InSure ONE Test Card then serves as a means to transport the dried samples to the laboratory. The InSure ONE test detects human hemoglobin in toilet bowl water. The test is developed in the laboratory or medical professional office with appropriate quality control. The FOBT Controls (K101831) are recommended for use as external controls.

Components of InSure® ONE™ – One Day Fecal Immunochemical Test:

a. The InSure® ONE™ Collection Kit* contains:
    - InSure® ONE™ Instructions for Use-Patient
    - InSure® ONE™ Test Card
    - Brush Kit containing 2x brushes and a waste bag
    - Business reply form and envelope

b. The InSure® ONE™ or InSure® FIT Developer Kit* (for development and interpretation of the test) contains:
    - InSure® ONE™ Instructions for Use-Professional Laboratory
    - InSure® ONE™ Test Strips: The Test Strips contain mouse monoclonal anti-human hemoglobin test line antibodies and a conjugate-specific polyclonal (donkey anti-goat) antibody control line, and a conjugate of anti-human hemoglobin polyclonal (goat) antibodies bound to colored (colloidal gold) particles.
    - InSure® ONE™ Run Buffer: Contains borate salts, ethanol, bovine serum albumin, and sodium azide as preservative.

c. The InSure® ONE™ or InSure® FIT FOBT Controls contains:
    - Instructions for Use
    - Positive Control
    - Negative Control

    **The above kits and components are supplied in a variety of packaging configurations and sold in combination or separately to meet customer requirements.*

Intended Use

The InSure® ONE™ is a fecal immunochemical test (FIT) that qualitatively detects human hemoglobin from blood in fecal samples. The samples will generally be collected by the test subject at home and the test developed at laboratories or professional offices. The InSure® ONE™ test is used to aid in the detection of lower gastrointestinal bleeding.

Analytical Sensitivity

The InSure® ONE™ reliably detects 50µg hemoglobin/gram stool for up to 14 days after sample collection.

Assay Cut-off Study

Fecal test samples were prepared by spiking stool samples with human blood of known hemoglobin concentration, to obtain the following fecal hemoglobin concentrations: 0 µg Hb/g stool, 5 µg Hb/g stool, 10 µg Hb/g stool, 20 µg Hb/g stool, 30 µg Hb/g stool, 40 µg Hb/g stool, 50 µg Hb/g stool, 60 µg Hb/g stool and 80 µg Hb/g stool. Pre-measured quantities of stool spiked with different levels of hemoglobin were placed in a pre-measured volume of water to simulate toilet water in which stool will be deposited. Following deposition of the stool, water samples were taken at 2 minutes with the InSure sample collection brushes and applied to Test Cards using the InSure FIT and the InSure ONE sampling procedures. Testing was performed side-by-side with the predicate by comparing the test results of the device with that of the predicate. Test Cards were prepared on Day 0, stored at room temperature (20–25°C) and developed on Day 5 to simulate the time span between the patient collecting the fecal water sample on the Test Card and transporting the sampled Test Card to the laboratory by mail. The cut-off was determined to be 50 µg hemoglobin/g stool.

Cut-off Study

Hb Concentration (ng/mL)	N	InSure ONE		Negative Percent Agreement (95% CI[1])	Positive Percent Agreement (95% CI[1])
		Negative	Positive		
0	40	40	0	100% (91.2% to 100%)	0% (0% to 8.8%)
5	40	38	2	95.0% (83.5% to 98.6%)	5.0% (1.4% to 16.5%)
10	40	31	9	77.5% (62.5% to 87.7%)	22.5% (12.3% to 37.5%)
20	40	19	21	47.5% (32.9% to 62.5%)	52.5% (37.5% to 67.1%)
30	40	8	32	20.0% (10.5% to 34.8%)	80.0% (65.2% to 89.5%)
40	40	3	37	7.5% (2.6% to 19.9%)	92.5% (80.1% to 97.4%)
50	40	1	39	2.5% (0.4% to 12.9%)	97.5% (87.1% to 99.6%)
60	40	1	39	2.5% (0.4% to 12.9%)	97.5% (87.1% to 99.6%)
80	40	0	40	0% (0% to 8.8%)	100% (91.2% to 100%)

CI=confidence interval, Hb=hemoglobin

[1] Wilson Score

Method Comparison

A method comparison of InSure® ONE™ with the predicate test, InSure® FIT™, was conducted to determine if there was a significant difference in test performance between sampling two separate fecal samples once each or a single fecal sample, sampled twice, for detection of occult blood. Patients were recruited from three intended use sites and the study was performed at one intended use site in Australia. A total of 859 patients collected fecal water samples using both InSure FIT and InSure ONE Test Cards before undergoing colonoscopy. Test Card A was the InSure FIT sampling procedure, the predicate device. Test Card B and Test Card C was the InSure ONE sampling procedure, the test device.

Tissue samples collected at colonoscopy were histopathologically examined for the type of lesion (i.e., cancer, advanced adenoma, etc.). Statistical analysis of the test results for clinical positive predictive value (PPV) and clinical negative predictive value (NPV) showed that the InSure ONE test results have acceptable overall agreement with InSure FIT test results. The study demonstrated that there were no statistically significant differences in the test results obtained from two fecal water sample aliquots taken from one bowel movement (new sampling method InSure ONE), when compared to one fecal water sample aliquot taken from two separate bowel movements (predicate sampling method InSure FIT). The InSure ONE test is substantially equivalent to the predicate device.

Summary

The InSure ONE One Day Fecal Immunochemical test has the same intended use, technological characteristics as the predicate device, InSure FIT. The InSure ONE is an easy to use screening method to reliably detect human hemoglobin from blood in toilet bowl water containing defecated stool that may be an indication of gastrointestinal pathology. The clinical performance of the InSure ONE sampling and test method support a substantial equivalence claim.