January 2, 2020

Eiken Chemical Co., Ltd.
Tadashi Yasuda
Manager
4-19-9, Taito
Taito-ku, Tokyo 110-8408 Japan

Re: K191147
Trade/Device Name: OC-Auto Sensor io iFOB Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: OOX
Dated: April 26, 2019
Received: April 30, 2019

Dear Tadashi Yasuda:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lea Carrington
Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191147

Device Name
OC-Auto Sensor io iFOB Test

Indications for Use *(Describe)*
"OC-Auto Sensor io iFOB Test" is designed to be used together as an immunoassay test system. The test system is intended for the qualitatitve detection of fecal occult blood in feces by professional laboratories. The automated test is used for the measurement of fecal occult blood and is useful as an aid to detect blood in stool when lower gastrointestinal bleeding may be suspected.

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"

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

510(k) Submitter Information:

Name: EIKEN CHEMICAL CO., LTD
Address: 4-19-9, Taito, Taito-ku, Tokyo 110-8408, Japan
Phone: 81-3-58463479
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Contact Name & Info: Tadashi Yasuda
Regulatory Affairs Department
regulatoryaffairs@eiken.co.jp

Date Prepared: December 19, 2019

Device Information:

Trade Name: OC-Auto Sensor io iFOB Test
Common Name: Automated Occult Blood Analyzer
Classification Name: Occult Blood Test (21 CFR 864.6550, Product Code: OOX)
Device Class: Class II
510(k) Number: K191147
Manufacturer: Eiken Chemical Co., Ltd.

Predicate Device Information:

Trade Name: OC-Sensor DIANA iFOB Test
510(k) Number: K092330
510(k) Applicant: Eiken Chemical Co., Ltd.
Manufacturer: Eiken Chemical Co., Ltd.
Repackager/Relabeler: Polymedco Inc.

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Intended Use:

"OC-Auto Sensor io iFOB Test" is designed to be used together as an immunoassay test system. The test system is intended for the qualitatitve detection of fecal occult blood in feces by professional laboratories. The automated test is used for the measurement of fecal occult blood and is useful as an aid to detect blood in stool when lower gastrointestinal bleeding may be suspected.

Device Description:

OC-Auto Sensor io iFOB Test is intended for the automated *in vitro* qualitative detection of fecal occult blood in feces by professional laboratories. The test system is comprised of test reagents (latex, diluent buffer, wash concentrate, calibrator, negative and positive controls), sample collection bottles and analyzer.

The principle of measurement employed for the reagent system is latex agglutination. A latex agglutination reaction is the clumping of antigen- or antibody-sensitized polystyrene latex particles through an antigen-antibody reaction. A light beam is passed through the reaction liquid to measure changes in the intensity of the transmitted light beam (latex turbidimetry), and changes in the intensity of the scattered light beam (latex nephelometry). With OC-Auto Sensor io iFOB Test analyzer, latex turbidimetry is used to measure the amount of an antigen or an antibody by measuring changes in scattered light rays in latex agglutination.

The throughput of the instrument is 88 samples per hour. The samples are collected in the sample collection bottles that are sent home with the patient. The sample collection bottles are then returned to the laboratory. The inverted sample collection bottles are racked and placed onto the instrument platform. The sample collection bottle is punctured and a sample is pipet into the cuvette followed by the latex reagent and mixed. Measurements are taken between the mixing cycles. After a series of washes the blank is read and the final results calculated and printed.

Components of OC-Auto Sensor io iFOB Test System:

Analyzer
The analyzer can be operated by selecting the icons displayed on the operation panel. Operators are encouraged to follow the accompanied instruction manual.

Latex Reagent
Prepared by sensitizing anti-human HbA0 antibodies to polystyrene latex particles. When the reagent is mixed with sample, the anti-human HbA0 antibodies that were sensitized to latex react with the hemoglobin in the sample, resulting in a latex agglutination reaction. The

reaction is then analyzed by optical density, with the amount of the change increasing in proportion to higher concentration of HbA0 in the sample.

Latex Reagent contains latex sensitized with polyclonal antibodies to human hemoglobin. One vial contains 7 mL of reagent. It shall be stored at 2-8 °C and is stable through its labeled shelf-life.

Diluent Buffer
One vial contains 200 mL of buffer. One vial contains 2.38 g of HEPES. It shall be stored at 2-8 °C and is stable through its labeled shelf-life.

Wash Concentrate
Aqueous detergent capable of dissolving protein deposits within the fluid path during the cleaning routine. The wash concentrate contains 120 mL of a concentrated wash that is diluted to 500 mL prior to use. The final wash solution concentration contains less than 5 % Sodium Hypochlorite. It shall be stored at room temperature and is stable through its labeled shelf life.

Calibrator
Contains 3 mL of 1,000 ng/mL purified hemoglobin in buffer. The HbA0 is derived from human blood. The blood is tested for HBS antigens, HIV (HIV-1 and HIV-2) antibodies and HCV antibodies, and only blood that tests negative for the presence of these agents is used. The Calibrator is serially diluted prior to analysis with Diluent Buffer to construct a calibration curve. It shall be stored at 2-8 °C and is stable through its labeled shelf-life.

Positive Control
Contains 5 mL of purified hemoglobin targeted around 150 ng/mL and 450 ng/mL in buffer. It shall be stored at 2-8 °C and is stable through its labeled shelf-life.

Negative Control
Contains 1 mL of buffer. It shall be stored at 2-8 °C and is stable through its labeled shelf-life.

Sampling Bottle
Plastic bottle for collecting fecal sample. It contains 2 mL of extraction buffer.

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Device Characteristics in Comparison with the Predicate Device:

The table below provides a summary of the device characteristics for OC-Auto Sensor io iFOB Test and the predicate device.

Similarities		
Device	OC-Auto Sensor io iFOB Test (k191147)	Predicate (k092330)
Manufacturer	Eiken Chemical Co., Ltd.	Eiken Chemical Co., Ltd.
Intended Use	Intended for the qualitative detection of fecal occult blood in feces by professional laboratories. The automated test is used for measurement of fecal occult blood and is useful as an aid to detect blood in stool when lower gastrointestinal bleeding may be suspected.	Intended for the qualitative detection of fecal occult blood in feces by professional laboratories.
Indications for Use	Same as intended use	The automated test is used for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal disorders (GI), e.g. colitis, polyps, and colorectal cancer. The OC-Sensor DIANA iFOB Test is recommended for use in 1) routine physical examinations, 2) monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding.
Sample Type	Feces in an extraction buffer	Feces in an extraction buffer
Test Principle	Measurement of hemoglobin antibody-antigen reaction by latex turbidimetry.	Measurement of hemoglobin antibody-antigen reaction by latex turbidimetry.
Detection Level	20 µg hHb/g stool (100 ng hHb/mL buffer)	100 ng/mL hHb in fecal extraction buffer
Latex Reagent	Anti-human HbA0 antibodies sensitized to polystyrene latex particles	Anti-human HbA0 antibodies sensitized to polystyrene latex particles

Differences		
Device	OC-Auto Sensor io iFOB Test	Predicate (k092330)
Analyzer		
Dimension	W360 x D560 x H425 (mm)	W630 x D560 x H560 (mm)
Weight	35 kg	60 kg
Power Required	AC100-240V, 150 VA	AC100-240V, 500VA
Operating System	NORTi Ver.4.0	Windows XP Embedded Adv.
Through-put	88 samples / hour	280 samples / hour
Sample Rack	20 samples: 5 samples x 4 racks	150 samples: 10 samples x 15 racks
Reaction Cuvette	Disposable acrylic cuvette (10 serial cell cuvette)	Semi-disposable acrylic cuvette (11 serial cells x 5 cuvettes)
Cell Cleaning Units	Not included	Included
Buffer Bottle Volume	200 mL	500 mL
Latex Reagent Bottle Volume	7 mL	15 mL
Calibrator Concentration (top)	1000 ng Hb/mL	2000 ng Hb/mL
# of Calibration Points	5 points	6 points
Hb Conc. of Calibration Points	0, 50, 200, 500, 1000 ng Hb/mL	0, 62.5, 125, 250, 500, 1000 ng Hb/mL

Performance Characteristics

Precision/Reproducibility

The tests were performed in-house and in three intended use sites using different lots of reagents, and different analyzers. The samples measured were control stool samples with added hemoglobin concentrations at 0, 50, 80, 100, 120, 450 and 700 ng/mL (hereafter, the seven known concentrations). The tests were performed by personnel in each site and to exclude bias, the concentrations of the samples were kept blind from the operators.

Calibrators are prepared by diluting with calibrator diluent, then they are measured in triplicate. This calibration curve is used throughout the procedure of 20 days. The samples are measured in replicates of 21. The same measurement is done in the morning and in the afternoon in one day for total of 20 days. All test results satisfied the acceptance criteria.

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Overall Precision:

	Sample concentration	Expected value	Observed positive number	Observed negative number	Total number	positive percentage agreement	95%CI	Negative percentage agreement	95%CI	Overall percentage agreement	95%CI
inhouse	0ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	50ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	80ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	100ng/mL	negative/positive	466	374	840					100.0%	99.9% ~ 100.0%
	120ng/mL	positive	838	2	840	99.8%	99.1% ~ 99.9%				
	450ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
	700ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
Study Site 1	0ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	50ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	80ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	100ng/mL	negative/positive	395	445	840					100.0%	99.9% ~ 100.0%
	120ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
	450ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
	700ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
Study Site 2	0ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	50ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	80ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	100ng/mL	negative/positive	80	760	840					100.0%	99.9% ~ 100.0%
	120ng/mL	positive	839	1	840	99.9%	99.3% ~ 100.0%				
	450ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
	700ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
Study Site 3	0ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	50ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	80ng/mL	negative	0	840	840			100.0%	99.5% ~ 100.0%		
	100ng/mL	negative/positive	39	801	840					100.0%	99.9% ~ 100.0%
	120ng/mL	positive	838	2	840	99.8%	99.1% ~ 99.9%				
	450ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
	700ng/mL	positive	840	0	840	100.0%	99.5% ~ 100.0%				
all sites (inhouse not included)	0ng/mL	negative	0	2520	2520			100.0%	99.9% ~ 100.0%		
	50ng/mL	negative	0	2520	2520			100.0%	99.9% ~ 100.0%		
	80ng/mL	negative	0	2520	2520			100.0%	99.9% ~ 100.0%		
	100ng/mL	negative/positive	514	2006	2520					100.0%	99.9% ~ 100.0%
	120ng/mL	positive	2517	3	2520	99.9%	99.7% ~ 100.0%				
	450ng/mL	positive	2520	0	2520	100.0%	99.9% ~ 100.0%				
	700ng/mL	positive	2520	0	2520	100.0%	99.9% ~ 100.0%				

Linearity

Hemoglobin dilution in series, 100 ng/mL increments of the range 100-1,000 ng/mL, was prepared by diluting a calibrator that has concentration of 1,000 ng/mL with the diluent. The samples were measured in triplicate. The measured values were treated as regression values and compared against theoretical values (intended hemoglobin concentration from dilution). The test results satisfied the criteria.

Prozone Effect

Susceptibility to prozone effects was evaluated by testing stool samples with hemoglobin concentration at 975, 1953, 3906, 7813, 15625, 31250, 62500, 125000, 250000, 500000 ng/mL. Each sample was measured in triplicate. The test results showed that the device is not susceptible to prozone effect up to 1953 ng/mL.

Limit of Detection

Hemoglobin negative samples and samples with 10 ng/mL increments up to 60 ng/mL of 21 replicates are measured for three days (Day 1, 2, and 3), using three lot sets of reagents. From the study, 20 ng/mL was determined as the limit of detection.

Hemoglobin Variants

Negative stool samples spiked with the seven known concentrations of hemoglobin S, C, and F were measured in 21 replicates respectively. The test results showed that the device is

equally sensitive to hemoglobin S, C, and F.

Cross Reactivity – Animal Hemoglobin

600 ng/mL of animal hemoglobin (bovine, equine, porcine, goat, sheep, rabbit, turkey, and fish) were added to stool samples spiked with the seven known concentrations of human hemoglobin. The samples were measured in 21 replicates. The test results showed no cross reactivity with the tested animal hemoglobin.

Cross Reactivity – Vegetable Extracts

Vegetables known to have peroxidase activities, broccoli, cauliflower, cantaloupe, horseradish, red radish, parsnip, and turnip were tested. Extracts with 2.5% concentration of broccoli, cantaloupe, horseradish, red radish, and parsnip and 3.3% concentration of cauliflower and turnip were added to stool samples spiked with the seven known concentrations of human hemoglobin. The samples were measured in 21 replicates. The test results showed no cross reactivity with the tested vegetable extracts.

Interference – Animal Meat Extracts

Extracts with 2.0% concentration of beef, pork, chicken, lamb, and fish, and 2.5% concentration of rabbit were added to stool samples spiked with the seven known concentrations of human hemoglobin. The samples were measured in 21 replicates. The test results showed no interference with the tested meat extracts.

Interference – Toilet Cleaners

10 mg/mL concentration of Nuriper, and Lysol Bleach, and 1.3 mg/mL concentration of Blue Enzyme were added to stool samples spiked with the seven known concentrations of human hemoglobin. The samples were measured in 21 replicates. The test results showed no interference with the tested toilet cleaners.

Interference – Drugs and Dietary Supplements

3.1 µg/mL of Iron, 2 µg/mL of Vitamin C, 0.2 µg/mL of laxative, 2 mg/mL of glycerol concentration for enema, and 25 µg/mL of peroxidase were added to stool samples spiked with the seven known concentrations of human hemoglobin. The samples were measured in 21 replicates. The test results showed no interference with the tested drugs and dietary supplements.

Stability Studies

Real Time Stability – Reagents (Latex Reagent and Buffer)

Reagents (latex reagent and buffer) were stored at 2°C and 8°C, respectively for 13 months. Measurements were performed initially (at day 0), after 6 months, 12 months, and 13 months of storage, using stool samples spiked with the seven known concentrations of human hemoglobin. The samples were measured in 21 replicates. The test results showed that the reagents are stable for 12 months at 2-8°C.

Real Time Stability – Calibrator
Calibrator was stored at 2°C and 8°C, respectively for 13 months. Measurements were performed initially (at day 0), after 6 months, 12 months, and 13 months of storage. The test results showed that the calibrator is stable for 12 months at 2-8°C.

Real Time Stability – Controls
Positive and negative controls were stored at 2°C and 8°C, respectively for 13 months. Measurements were performed initially (at day 0), after 6 months, 12 months, and 13 months of storage. The test results showed that the controls are stable for 12 months at 2-8°C.

Real Time Stability – Sampling Bottle
Sampling bottles were stored at 2°C and 30°C, respectively for 19 months. Measurements were performed initially (at day 0), after 9 months, 18 months, and 19 months of storage. At each time point, stored bottles were taken out of incubator, let to come to room temperature, and stool samples with the seven known hemoglobin concentration were added for 21 replicates. The test results showed that the sampling bottle is stable for 18 months at 2-30°C.

Reagent – Open Bottle Stability
Reagents (latex reagent and buffer) were opened and kept at 25°C for eight days. Stool samples with the seven known hemoglobin concentration were measured in 21 replicates at day 0, 4, 7, and 8 using the reagents. The test results showed that the reagents are stable after opened and kept on-board for 7 days.

Inoculated Native Sample Stability
Hemoglobin positive stool from two donors was mixed and positive pool sample was prepared. It was mixed with hemoglobin negative stool in sampling buffer to make 0.5 % stool sample with 6 hemoglobin concentrations that are close to 50, 80, 100, 120, 450, 700 ng/mL. Hemoglobin negative sample was made by mixing hemoglobin negative stool in sampling buffer with same percentage of stool. One set of samples consists of seven concentration levels and each set is stored at 25, 28, 30 and 33°C, respectively to test stability in room temperature at 7, 15, and 16 days for a 15-day claim. Another set was stored at 1, 4, 8, and 10°C, respectively to test stability in refrigerated temperature at 15, 30 and 31 days for a 30-day claim. The test results showed that samples collected in the sampling bottles are stable for 15 days when stored at room temperature, and 30 days when they are refrigerated.

Inoculated Sample Shipping Test
Sample shipment under extreme heat condition was simulated based on the temperature log taken in summer from a home mailbox to a medical laboratory where the measurement takes place. The test simulation is made at 110 % of the actual temperature, and the end point is set at 16 days from the sampling to cover the 15-day sample stability claim at room temperature. The tested samples were prepared in the same ways as described in the sample stability study. The test results showed that the samples collected in the sampling bottles are stable for 15 days during shipment under the simulated extreme heat condition.

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Humidity Effect on Stability

The reagents (latex, buffer, calibrator, and controls) were stored under three humidity condition (25%, 50%, and 80%, all at 23°C for 15 days which corresponds to 13 months storage at 8°C by Arrhenius equation) to evaluate the effect of humidity to the reagents. The test results showed that there were no effect of humidity to the reagents.

Method Comparison

Two sampling bottles, one for the device and one for the predicate were used for sampling per a fecal sample and the measurements were performed on their analyzers, respectively. The method comparison study was performed at one professional medical laboratory in the U.S. and two international professional medical laboratories. For total of 425 samples with which included 20 CRC patients samples, between the results obtained with the device and the predicate, the overall percent agreement (OPA) was 100 % (95 % CI 99.1 – 100 %), with positive percent agreement (PPA) 100 % (95 % CI 96.9 – 100 %), and negative percent agreement (NPA) 100 % (95 % CI 98.8 – 100 %). The study demonstrated that the analytical performance of the device is substantially equivalent to the predicate.

Study site	New Test	Predicate Test			Overall Percent Agreement (95 % CI)	Positive Percent Agreement (95 % CI)	Negative Percent Agreement (95 % CI)
	OC-SENSOR io	OC-SENSOR DIANA					
		Positive Results	Negative Results	Total Results			
Study site 1	Positive Results	50	0	50	100%	100%	100%
	Negative Results	0	100	100			
	Total Results	50	100	150	(97.5 % - 100 %)	(92.9 % - 100 %)	(96.3 % - 100 %)
Study site 2	Positive Results	25	0	25	100%	100%	100%
	Negative Results	0	100	100			
	Total Results	25	100	125	(97.0 % - 100 %)	(86.7 % - 100 %)	(96.3 % - 100 %)
Study site 3	Positive Results	30	0	30	100%	100%	100%
	Negative Results	0	100	100			
	Total Results	30	100	130	(97.1 % - 100 %)	(88.6 % - 100 %)	(96.3 % - 100 %)
Combined	Positive Results	105	0	105	100%	100%	100%
	Negative Results	0	300	300			
	Total Results	105	300	405	(99.1 % - 100 %)	(96.5 % - 100 %)	(98.7 % - 100 %)

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Description	New Test	Predicate Test			Overall Percent Agreement (95 % CI)	Positive Percent Agreement (95 % CI)	Negative Percent Agreement (95 % CI)
	OC-SENSOR io	OC-SENSOR DIANA					
		Positive Results	Negative Results	Total Results			
CRC patients' sample	Positive Results	15	0	15	100%	100%	100%
	Negative Results	0	5	5			
	Total Results	15	5	20	(83.9 % - 100 %)	(79.6 % - 100 %)	(56.6 % - 100 %)
All samples combined	Positive Results	120	0	105	100%	100%	100%
	Negative Results	0	305	300			
	Total Results	120	305	425	(99.1 % - 100 %)	(96.9 % - 100 %)	(98.8 % - 100 %)

Cybersecurity:

OC-Auto Sensor io analyzer has no network connecting function, therefore free from cyberattacks via network. The analyzer is equipped with USB memory terminal and RS-232C terminal, however these terminals can only be used for data output and have no read functions.

Electromagnetic Compatibility (EMC):

OC-Auto Sensor io analyzer passed the tests performed at Power Frequency Magnetic Field 30 A/m and Electrostatic Discharge ±2 kV, ±4 kV, ±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air.

Conclusion:

OC-Auto Sensor io iFOB Test does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate.