July 8, 2021

First Light Diagnostics, Inc.
% Fran White
President, Regulatory Affairs
MDC Associates, LLC
180 Cabot Street
Beverly, Massachusetts 01915

Re: K193490
Trade/Device Name: SensiTox C. difficile Toxin Test
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism Differentiation And Identification Device
Regulatory Class: Class I
Product Code: LLH
Dated: December 16, 2019
Received: December 17, 2019

Dear Fran White:

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,

Ribhi Shawar, Ph.D. (ABMM)
Chief,
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193490

Device Name
SensiTox C. difficile Toxin Test

Indications for Use *(Describe)*
The SensiTox C. difficile Toxin Test is an immunofluorescence assay intended for the qualitative detection of Clostridioides difficile toxins A and/or B in human stool specimens. The test is intended as an aid in the diagnosis of C. difficile infection (CDI) in patients exhibiting symptoms of CDI. Negative results do not preclude toxigenic C. difficile infection. The SensiTox C. difficile Toxin Test should not be used as the sole basis for treatment or other management decisions. The test can only be used with the MultiPath platform.

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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2.0 510(k) SUMMARY

Date of Summary: June 30, 2021

Product Name: SensiTox™ *C. difficile* Toxin Test

Sponsor:
First Light Diagnostics
2 Omni Way
Chelmsford, MA 01824

Correspondent:
MDC Associates, Inc.
Fran White, President Regulatory Affairs
180 Cabot Street
Beverly, MA 01915
Phone: (978) 927 3808
Fax: (866) 540 3448
Email: regulatory@mdcassoc.com

Common Name: Microorganism differentiation and identification device

Regulation Number: 866.2660

Classification: LLH, Class I

Substantial Equivalency

Description	First Light Diagnostics Subject Device SensiTox *C. difficile* Toxin Test	Meridian Bioscience, Inc. Predicate Device K041003 ImmunoCard® Toxins A & B
Regulation	866.2660	Same
Product Code	LLH	Same
Device Class	Class I	Same
Panel	83 Microbiology	Same
Intended Use	The SensiTox *C. difficile* Toxin Test is an immunofluorescence assay intended for the qualitative detection of *Clostridioides difficile* toxins A and/or B in human stool specimens. The test is intended as an aid in the diagnosis of *C. difficile* infection (CDI) in patients exhibiting symptoms of CDI. Negative results do not preclude toxigenic *C. difficile* infection. The SensiTox *C. difficile* Toxin Test should not be used as the sole basis for treatment or other management decisions. The test can only be used with the MultiPath platform.	ImmunoCard® Toxins A & B is a rapid, qualitative, horizontal-flow enzyme immunoassay (EIA) for detecting *Clostridium difficile* toxins A and B in human stool. This assay is used as an aid in the diagnosis of *C. difficile*-associated disease.

Description	First Light Diagnostics Subject Device SensiTox *C. difficile* Toxin Test	Meridian Bioscience, Inc. Predicate Device K041003 ImmunoCard® Toxins A & B
Similarities		
Sample Type	Human Stool	Same
Analyte	Toxin A and B	Same
Prescription Required?	Prescription use only	Same
Setting	Clinical laboratory	Same
Differences		
Technology	Immunofluorescent assay	Enzyme immunoassay
Antibodies	Detection & Capture: Mouse monoclonal anti-toxin A and B	Goat polyclonal anti-toxin B
Test format	Fluidic cartridge with direct digital imaging	Lateral flow with visual interpretation

Intended Use
The SensiTox *C. difficile* Toxin Test is an immunofluorescence assay intended for the qualitative detection of *Clostridioides difficile* toxins A and/or B in human stool specimens. The test is intended as an aid in the diagnosis of *C. difficile* infection (CDI) in patients exhibiting symptoms of CDI. Negative results do not preclude toxigenic *C. difficile* infection. The SensiTox *C. difficile* Toxin Test should not be used as the sole basis for treatment or other management decisions. The test can only be used with the MultiPath platform.

Limitations
For prescription use only. Please refer to the SensiTox *C. difficile* Toxin Test labeling for a more complete list of warnings, precautions, and contraindications.

Methodology
The SensiTox *C. difficile* Toxin Test detects toxins A and B in stool samples using an immunofluorescence assay and the proprietary MultiPath detection technology. The assay is performed on the proprietary MultiPath Analyzer.

A stool sample, collected in a dry, clean, and leakproof collection device, without any collection media, is used for the test. The stool sample is added to Stool Specimen Diluent containing Protease Inhibitor and processed manually through a spin column to remove particulates. The stool filtrate is added to the SensiTox *C. difficile* Cartridge, a single use consumable that contains all the reagents required to run a single test. The Cartridge is loaded onto the MultiPath Analyzer for processing through the steps of the assay.

Once loaded onto the Analyzer, the barcodes on the Cartridge that identify the test type and associated test specific information (manufacturer installed barcode) and sample (laboratory affixed barcode) are read. The cartridge is moved to the fluidics station where it is first heated to 35°C. The sample is then split into 6 equal aliquots in 6 distribution wells within the cartridge, 3 wells specific to toxin A and 3 wells specific to toxin B. The sample aliquots flow from the distribution wells to the reagent wells containing target specific antibody conjugated fluorescent and magnetic particles in the form of lyophilized beads. Upon contact with the sample, the lyophilized beads rehydrate and the reaction mixtures flow into the imaging wells, the bottoms of which are coated with a dye cushion reagent. Upon contact with the reagents, the dye-cushion dissolves forming a dense opaque aqueous layer that separates the sample and reagents from the bottom optical

surface of the Imaging Well. In the upper assay layer, the toxins, if present, bind to the magnetic and fluorescent particles tethering them together. The cartridge is incubated for 28 minutes to allow the reaction to take place and then is moved to the magnetics station. At the magnetics station, the imaging well is placed over permanent magnets that draw the magnetic particles and any fluorescent particles that are tethered to them via the target molecules through the dye-cushion layer, depositing them on the bottom imaging surface. The captured fluorescent particles are imaged and quantified using non-magnified digital imaging.

The Analyzer can be run in batch mode or by random access. Up to 20 cartridges can be loaded onto the Analyzer in parallel. The first result is reported in approximately 35 minutes of loading the cartridge onto the Analyzer with subsequent results being reported in 2.5 minute increments. The results are interpreted using the MultiPath applications software as valid or invalid, and if valid, the results are reported as toxin detected if either toxin A or B or both toxins are present or toxin not detected if neither toxin is present. Results are displayed on the instrument touch screen and can be printed.

Performance Data: Bench Studies

I. Limit of Detection (LoD)

The limit of detection (LoD) for *C. difficile* toxins A and B was determined by spiking negative pooled stool with commercially available purified toxins A and B. For each toxin, the LoD is defined as the lowest concentration of target that can be detected at a rate of ≥95%. The LoD was established by testing 5 dilutions of toxins A and B with 3 lots of reagents and 20 replicates per lot for a total of 60 replicates per concentration. The data from the 3 lots were combined to determine the positive hit rate. The LoD established for toxin A is 3.5 ng/mL and for toxin B is 50 ng/mL.

II. Reproducibility

The reproducibility of the SensiTox *C. difficile* Toxin Test was evaluated at 3 sites over the course of 5 days by 2 operators each day. Randomized and blinded samples comprised of Stool Specimen Diluent spiked with varying concentrations of both toxins A and B – low positive (1-2x LoD), moderate positive (2-4x LoD), high positive (5-8x LoD), and negative (unspiked) were prepared and provided to each participating site. Each operator mixed the designated sample with pooled stool prescreened and known to be negative for toxins A and B and processed the sample using the *C. difficile* test procedure. A total of 376 samples comprised of 95 negative samples and 281 positive samples was run with an overall reproducibility of 99.2% (Table 2.1). As shown in Table 2.2, the negative sample generated one false positive result and the low and moderate positive samples each generated one false negative result.

Site	Total Samples Run	# Correct Results	# Miscalls	# Invalids	% Accuracy	% Invalid
Site 1	123	123	0	3	100%	2.4%
Site 2	128	127	1	8	99.2%	6.3%
Site 3	125	123	2	5	98.4%	4.0%
Total	**376**	**373**	**3**	**16**	**99.2%**	**4.3%**

Table 2.1 Summary of reproducibility study data

Sample Description	Site 1		Site 2		Site 3		Total	
	#	%	#	%	#	%	#	%
Negative	30/30	100%	30/30	100%	29/30	96.7%	89/90	98.9%
Low	30/30	100%	29/30	96.7%	30/30	100%	89/90	98.9%
Moderate	30/30	100%	30/30	100%	29/30	96.7%	89/90	98.9%
High	30/30	100%	30/30	100%	30/30	100%	100/100	100%

Table 2.2 Reproducibility data by sample type

III. Analytical Reactivity (Inclusivity)

Analytical reactivity testing was conducted to ensure that the SensiTox *C. difficile* Toxin Test can detect multiple ribotypes of toxins A and B. Pooled stool samples that were prescreened and confirmed to be negative for toxins A and B were spiked with purified toxin from clinically important ribotypes and tested in triplicate in the SensiTox *C. difficile* Toxin Test. Six ribotypes of toxin A were tested at 15 ng/mL and 8 ribotypes of toxin B were tested at 300 pg/mL. Positive controls comprised of toxins A and B purified from the wildtype strain 087 also were tested. The results, summarized in Table 2.3, demonstrate that all toxin A and B ribotypes tested are detected in the SensiTox *C. difficile* Toxin Test.

Toxin Target	Ribotype	Toxin A	Toxin B
A	001	Detected	Not Detected
A	002	Detected	Not Detected
A	014	Detected	Not Detected
A	027	Detected	Not Detected
A	078	Detected	Not Detected
A	106	Detected	Not Detected
A	087 (control)	Detected	Not Detected
B	001	Not Detected	Detected
B	001	Not Detected	Detected
B	014	Not Detected	Detected
B	017	Not Detected	Detected
B	027	Not Detected	Detected
B	036	Not Detected	Detected
B	078	Not Detected	Detected
B	106	Not Detected	Detected
B	087 (control)	Not Detected	Detected

Table 2.3 Analytical reactivity of the SensiTox *C. difficile* Toxin Test

IV. Analytical Specificity

The analytical specificity of the SensiTox *C. difficile* Toxin Test was evaluated by testing cultured organisms (bacteria, yeast, viruses) in negative pooled stool or contrived stool containing 15 ng/mL of toxin A and 300 pg/mL of toxin B. Bacteria and yeast were tested at a concentration of $1x10^6$ CFU/mL and each virus was tested at a concentration of $1x10^5$ PFU/mL unless otherwise indicated in Table 2.4. All organisms were tested in triplicate in each study.

None of the organisms cross-react when tested in negative pooled stool in the SensiTox *C. difficile* Toxin Test. None of the organisms tested in the presence of contrived pooled stool negatively interfere with the detection of toxins A or B.

Species	Concentration Tested	Species	Concentration Tested
Adenovirus	$1x10^5$ PFU/mL	Enterovirus	$1x10^5$ PFU/mL
Aeromonas hydrophila	$1x10^6$ CFU/mL	*Escherichia coli*	$1x10^6$ CFU/mL
Bacillus cereus	$1x10^6$ CFU/mL	*Escherichia coli sero:0157*	$1x10^6$ CFU/mL
Bacillus subtilis	$1x10^6$ CFU/mL	*Escherichia coli type 026:H4*	$1x10^6$ CFU/mL
Bacteroides fragilis	$1x10^6$ CFU/mL	*Helicobacter pylori*	$1x10^6$ CFU/mL
Campylobacter jejuni	$1x10^6$ CFU/mL	*Klebsiella oxytoca*	$1x10^6$ CFU/mL
Campylobacter coli	$1x10^6$ CFU/mL	Norovirus	$7x10^4$ PFU/mL
Candida albicans	$1x10^6$ CFU/mL	*Peptostreptococcus anaerobius*	$1x10^6$ CFU/mL
Clostridium difficile (non-toxigenic)	$1x10^6$ CFU/mL	*Proteus vulgaris*	$1x10^6$ CFU/mL
Clostridium haemolyticum	$1x10^6$ CFU/mL	*Pseudomonas aeruginosa*	$1x10^6$ CFU/mL
Clostridium novyi	$1x10^6$ CFU/mL	Rotavirus	$1x10^5$ PFU/mL
Clostridium perfringens	$1x10^6$ CFU/mL	*Salmonella enterica (typhimurium)*	$1x10^6$ CFU/mL
Clostridium septicum	$1x10^6$ CFU/mL	*Serratia liquefaciens*	$1x10^6$ CFU/mL
Clostridium sordellii[1]	$1x10^6$ CFU/mL	*Shigella dysenteriae*	$1x10^6$ CFU/mL
Clostridium sporogenes	$1x10^6$ CFU/mL	*Shigella flexneri*	$1x10^6$ CFU/mL
Coxsackie-virus	$1x10^5$ PFU/mL	*Shigella sonnei*	$1x10^6$ CFU/mL
Cytomegalovirus	$1x10^5$ PFU/mL	*Staphylococcus aureus*	$1x10^6$ CFU/mL
Echovirus	$4x10^4$ PFU/mL	*Staphylococcus epidermidis*	$1x10^6$ CFU/mL
Enterobacter aerogenes	$1x10^6$ CFU/mL	*Vibrio cholera*	$1x10^6$ CFU/mL
Enterobacter cloacae	$1x10^6$ CFU/mL	*Vibrio parahaemolyticus*	$1x10^6$ CFU/mL
Enterococcus faecalis	$1x10^6$ CFU/mL		

Table 2.4 Organisms tested for analytical specificity

[1] The potential for purified *Clostridium sordellii* toxin to cross-react was not evaluated. It is unknown if *C. sordellii* toxin concentration in the 10^6 CFU/mL preparation that was tested falls below the limit of detection for the SensiTox *C. difficile* Toxin Test.

V. Interfering Substances

Negative pooled stool and contrived pooled stool containing 15 ng/mL of toxin A and 300 pg/mL of toxin B were spiked with potential interferents that can be found in stool. The interferents and the concentrations tested are listed in Table 2.5. None of the potential interferents negatively impact the performance of the SensiTox *C. difficile* Toxin Test, with the exception of Vancomycin. Vancomycin is not inhibitory at 40 mg/mL but was found to negatively impact the detection of toxins A and B at 50 mg/mL.

Potential Interfering Substance	Highest Concentration Tested and Shown to Not Interfere
Nystatin	500 U/mL (5% w/v)
Barium Sulphate	50 mg/mL(5% w/v)
Hydrocortisone	0.5 mg/mL (5% w/v)
Phenylephrine (Preparation H)	0.1 mg/mL (5% w/v)
Calcium Carbonate (Tums)	10.4 mg/mL (5% w/v)
Aluminum Hydroxide / Magnesium Hydroxide (Sunmark antacid)	1 mg/mL (5% v/v)
Loperamide Hydrochloride (Imodium)	3.3 µg/mL (5% v/v)
Bismuth Subsalicylate (Pepto Bismol)	0.2 mg/mL (5% v/v)
Sennosides (Senokot)	0.6 mg/mL (5% w/v)
Metronidazole in DMSO	50 mg/mL (5% w/v)
Vancomycin	40 mg/mL (4% w/v)
Mucin	50 mg/mL (5% w/v)
DMSO	10% v/v
Whole Blood	40% v/v

Table 2.5 Interferents and concentrations shown to not interfere with test

Clinical Performance Evaluation

The performance of the SensiTox C. *difficile* Toxin Test was evaluated in a prospective clinical study performed at three geographically diverse sites in the US using left over de-identified, unpreserved, stool specimens from patients suspected of having *C. difficile* infection. The performance of the test was evaluated in comparison to the cellular cytotoxicity neutralization assay (CCNA).

The overall clinical performance of the SensiTox *C. difficile* Toxin Test is summarized in Table 2.6 with the data broken down by clinical study site in Table 2.7. The sensitivity of the SensiTox *C. difficile* Toxin Test is 90.6% and the specificity is 95.7%.

		Cellular Cytotoxicity Neutralization Assay (CCNA)		
		Positive	*Negative*	*Total*
MultiPath *C. difficile* Assay	*Positive*	87	41	128
	Negative	9	909	918
	Total	96	950	1046
Sensitivity [95% CI]		90.6% [83.1% - 95.0%]		
Specificity [95% CI]		95.7% [94.2% – 96.8%]		
Positive Predictive Value [95% CI]		68.0% [59.5% - 75.4%]		
Negative Predictive Value [95% CI]		99.0% [98.1% - 99.5%]		

Table 2.6 Summary of clinical performance of SensiTox *C. difficile* Toxin Test

SITE	Samples (%)	CCNA Positive (%)	Percent (95% Score Confidence Interval)	
			Sensitivity	*Specificity*
Site 1	343 (32.8%)	28 (8.2%)	89.3% [72.8% - 96.3%]	95.2% [92.3% - 97.1%]
Site 2	449 (42.9%)	42 (9.4%)	85.7% [72.2% - 93.3%]	96.1% [93.7% - 97.6%]
Site 3	254 (24.3%)	26 (10.2%)	100% [87.1% - 100%]	95.6% [92.1% - 97.6%]
Total	1046	96 (9.2%)		

Table 2.7 Summary of clinical performance by participating clinical study site

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