510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K193490

B Applicant

First Light Diagnostics, Inc.

C Proprietary and Established Names

SensiTox *C. difficile* Toxin Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LLH	Class I	21 CFR 866.2660 - Microorganism Differentiation And Identification Device	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the SensiTox *C. difficile* Toxin Test.

B Measurand:

Clostridioides (Clostridium) difficile toxins A and B

C Type of Test:

Automated qualitative immunoassay

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The SensiTox *C. difficile* Toxin Test in 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

MultiPath Analyzer

IV Device/System Characteristics:

A Device Description:

The SensiTox *C. difficile* Toxin Test is a cartridge-based immunoassay intended to detect *C. difficile* toxin A and/or toxin B in stool samples from patients suspected of *C. difficile* infection (CDI). Each single-use test cartridge contains the lyophilized reagents required to perform three measurements each for *C. difficile* toxin A and toxin B: Total Signal Measurement, Neutralization Measurement, and Positive Control Measurement. The test kit also includes the following components used to prepare specimens for testing: *C. difficile* Stool Specimen Diluent, *C. difficile* Protease Inhibitor reagent, and Spin Columns for stool specimen manual filtration.

The assay is performed on the MultiPath Analyzer, which is an automated benchtop laboratory instrument intended for use by trained laboratory technicians. The Analyzer includes the following functionality: a barcode scanner for test-specific and specimen-specific information, a pneumatic system that drives fluidics within the test cartridge, a magnetic station that deposits magnetically-tagged fluorescent targeted molecules onto the cartridge imaging surface, an optical system to detect deposited fluorescent particles, and automated software to analyze the test measurement and interpret the results based on predefined signal measurement thresholds for Toxin A and Toxin B total signals and neutralization measurements. The Analyzer uses a touch screen display User Interface to convey test information, status, instructions and user input. Up to five cartridges can be loaded onto the Analyzer at one time.

B Principle of Operation:

The SensiTox *C. difficile* Toxin Test uses separate monoclonal antibodies that are conjugated to magnetic particles or fluorescent particles to capture and detect antigen, respectively. Labeled antibody-antigen complexes are deposited onto an imaging surface, and the MultiPath Analyzer uses digital imaging to automatically detect and interpret the assay signal.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   MultiPath Analyzer

2. Specimen Identification:

   The MultiPath Analyzer scans the two barcodes on the Cartridge: a manufacturer-provided barcode that identifies the test to be performed, along with the reagent lot information and a laboratory-generated barcode affixed by the user to identify the patient specimen.

3. Specimen Sampling and Handling:

   Stool specimens are manually diluted into corresponding Specimen Diluent tubes immediately before testing. The diluted specimen is added to a Spin Column tube labeled with the specimen identifier and centrifuged. The eluate is transferred to the Specimen Well of the Cartridge which is then placed in a multi-Cartridge rack that is loaded into the MultiPath Analyzer.

4. Calibration:

   The MultiPath Analyzer is calibrated by the manufacturer. Yearly maintenance is performed by qualified service personnel to clean, calibrate, test and verify the functionality of the device.

5. Quality Control:

   Internal Controls
   The *C. difficile* Cartridge contains two Internal Positive Control wells, one specific for Toxin A (5x LoD) and one specific for Toxin B (10x LoD), that ensure the sample matrix does not

negatively impact the performance of the test. An invalid result will be reported if the Internal Positive Control generates a signal below its defined threshold.

External Controls
The SensiTox *C. difficile* External Controls Kit containing positive and negative controls is provided separately. The positive control consists of lyophilized purified Toxin A and Toxin B in a buffered solution and the negative control consists of buffered solution. The External Controls are used periodically to verify performance of the reagents and the MultiPath Analyzer. It is recommended that External Controls be tested at least once every 30 days, when a new reagent lot is received in the laboratory, and when the MultiPath Analyzer undergoes installation, repair or maintenance procedures. External Controls should be tested in accordance with all institutional, local, state, federal, and accrediting agency guidelines.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Immunocard Toxins A & B, Model 712050

B Predicate 510(k) Number(s):
K041003

C Comparison with Predicate(s):

Device & Predicate Device(s):	**DEVICE K193490**	**PREDICATE K041003**
Device Trade Name	SensiTox *C. difficile* Toxin Test	ImmunoCard Toxins A & B
General Device Characteristic Similarities		
Intended Use/Indications For 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	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.

Device & Predicate Device(s):	DEVICE K193490	PREDICATE K041003
	treatment or other management decisions. The test can only be used with the MultiPath platform.	
Analyte	Same	*C. difficile* toxins A and B
Specimen type	Same	Human Stool
Interpretation	Same	Qualitative
General Device Characteristic Differences		
Test format	Cartridge-based immunofluorescence immunoassay with automated interpretation	Lateral flow enzyme immunoassay with visual interpretation
Antibodies	Capture and Detection: Mouse monoclonal anti-toxin A and B antibodies	Capture: Monoclonal anti-toxin A and goat polyclonal anti-toxin B antibodies Detection: Goat polyclonal anti-toxin A and B antibodies
Automated	Yes	No
Instrument	Multipath Analyzer	None

VI Standards/Guidance Documents Referenced:

- IEC 60601-1-2:2014 *General Requirements for Basic Safety and Essential performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- ANSI/AAMI/IEC 62304:2006 & A1:2016 (Consolidated Text): *Medical Device Software - Software Life Cycle Processes*
- ISO 14971 (3rd Edition): *Medical devices — Application of risk management to medical devices*
- ISO/IEC 24778:2008: *Information technology — Automatic identification and data capture techniques — Aztec Code bar code symbology specification*

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The reproducibility of the SensiTox *C. difficile* Toxin Test was evaluated at three sites over five days by two operators each day. The sample panels consisted of Stool Specimen Diluent aliquots spiked with both Toxins A and B at the following concentrations: low positive (1-2x LoD), moderate positive (2-4x LoD), high positive (5-8x LoD), and negative (unspiked). The panels were randomized and masked and then distributed to each site. Prior to testing, each operator mixed the designated sample with pooled stool matrix that was prescreened and known to be negative for *C. difficile* Toxins A and B. The samples were processed according to the labelled test procedure and tested with the SensiTox *C. difficile* Toxin Test in triplicate for a total of 90 observations per panel member. The qualitative test results for detecting Toxin A (**Table 1**), Toxin B (**Table 2**) and each panel member (i.e., detection of Toxin A or B, Table 3. Reproducibility – **Table 3**) are summarized below.

Overall, 16/360 (4.4%) samples initially produced invalid results in the study. All samples were valid upon retest following labeled instructions. All high positive panel members produced the expected positive results for both toxin A and B (90/90, 100%). For the moderate positive panel members, one sample produced false negative results for both toxin A and B at one site (89/90, 98.9%). Also, one negative sample at the same site produced false positive results for both toxin A and B (89/90, 98.9%). For the low positive panel members, one sample produced a false negative result for toxin A at one site (89/90, 98.9%), and all sites produced the expected positive result for toxin B (90/90, 100%).

Table 1. Reproducibility – Toxin A

Toxin A Panel	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%	90/90	100%

Table 2. Reproducibility – Toxin B

Toxin B Panel	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%	30/30	100%	30/30	100%	90/90	100%
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%	90/90	100%

Table 3. Reproducibility – Per Panel Member

Toxin B Panel	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%	90/90	100%

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Interfering substances
Endogenous and exogenous substances commonly found in stool were evaluated for their potential effect on the performance of the SensiTox *C. difficile* Toxin Test. Negative pooled stool and contrived positive pooled stool containing 15 ng/mL of Toxin A (4x LoD) and 300 pg/mL of Toxin B (6x LoD) were tested unspiked (positive and negative control) as well as spiked with the potential interferents shown in **Table 4** and tested in triplicate.

All negative samples produced the expected negative results in the presence of each substance. One initial invalid result was observed in the presence of Metronidazole at 40 mg/mL (1/115, 0.9% initial invalid rate); however, the sample produced the valid expected result upon repeat testing (0% final invalid rate). Out of six sample replicates tested with Vancomycin at 50 mg/mL, one false negative Toxin A result and one false negative Toxin B result were observed. No assay interference was observed in the presence of Vancomycin at 40 mg/mL or in the presence of the other substances at the concentrations tested.

Table 4. Potential Interfering Substances

Potential Interfering Substance	Concentration Tested
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

Analytical Specificity
The analytical specificity of the SensiTox *C. difficile* Toxin Test was evaluated by testing a panel of microorganisms commonly found in stool samples (**Table 5**). Cultured organisms were spiked into negative pooled stool or spiked into contrived positive stool containing 15 ng/mL Toxin A (4x LoD) and 300 pg/mL Toxin B (6x LoD). Bacteria and yeast were tested at $1x10^6$ CFU/mL and viruses were tested at $1x10^5$ PFU/mL, except for Norovirus ($7x10^4$ PFU/mL) and Echovirus ($4.1x10^4$ PFU/mL). All microorganisms were tested in triplicate with the SensiTox *C. difficile* Toxin Test. No false positive results were observed. Initial invalid results were obtained for four samples (4/135, 3.0% initial invalid rate), and all samples produced the expected valid result upon repeat (0% final invalid rate).

Table 5. Potential Interfering Microbes

Microorganism	Microorganism
Adenovirus	Enterovirus

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

[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.

Microbial Interference

Microbial interference was evaluated for the SensiTox *C. difficile* Toxin Test by using the same panel of microorganisms from in the analytical specificity study (**Table 5**) spiked into contrived positive stool containing 15 ng/mL Toxin A (4x LoD) and 300 pg/mL Toxin B (6x LoD). Toxins A and B were detected in all samples indicating lack of interference. However, one initial invalid result was observed (1/135, 0.7% initial invalid rate), and the sample produced the expected valid result upon retest per the study protocol and assay instructions (0% final invalid rate).

Hook Effect

A study was conducted with the SensiTox *C. difficile* Toxin Test to determine if high concentrations of target *C. difficile* toxins interfere with the test result (hook effect). Diluted toxins (Toxin A dilutions from 50 µg/mL – 2.5 ng/mL, Toxin B dilutions from 1.3 µg/mL – 66 pg/mL) were spiked into pooled negative stool and three replicates per dilution were tested with the SensiTox *C. difficile* Toxin Test. No false negative results were observed for either toxin at any concentration tested.

4. Assay Reportable Range:

Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Quality Control
The SensiTox *C. difficile* Toxin Test uses internal positive controls (individual wells specific to each toxin and contained within the test cartridge) as well as external positive and negative controls. Quality control procedures monitor the accuracy and precision of the analytical process. It is recommended that External Controls be tested at least once every 30 days, when a new reagent lot is received in the laboratory, and when the MultiPath Analyzer undergoes installation, repair or maintenance procedures. External controls are required but not provided with the SensiTox *C. difficile* Toxin Test.

A minimum of one positive and one negative external control were used each day prior to testing clinical specimens or performing analytical studies. Controls were processed in the same manner as clinical specimens and results interpreted in accordance with the SensiTox *C. difficile* Toxin Test software assay parameters. To pass, a positive control must detect both Toxins A and B while the negative control must generate a negative result for both, according to the instructions for use of the external control kit. During the clinical study, a total of 343 external controls were run (169 positive and 174 negative controls). Of the 343 controls tested, 10 generated invalid results (2.9% invalid rate). Of the 333 valid QC results, two were QC failures (i.e., incorrect result). Per the study protocol, when this occurred another control was tested and passed which made the clinical specimen data acceptable for analysis on those days.

MultiPath Analyzer
Additional assay and instrument parameters are monitored during a test run on the MultiPath Analyzer. These include sample input errors, instrument cartridge processing errors, and instrument system messages.

Specimen Stability
A study was conducted to evaluate the stability of stool samples that have been stored refrigerated at 2 – 8 °C for analysis with the SensiTox *C. difficile* Toxin Test. Seven individual stool samples and one pool of two stool samples were collected and confirmed negative for *C. difficile* A and B toxins with the SensiTox *C. difficile* Toxin Test. Sample aliquots were spiked with each target toxin individually at 15 ng/mL (4x LoD) for Toxin A and 250 pg/mL (5x LoD) for Toxin B. The samples were stored refrigerated and a minimum of three replicates each were tested with the SensiTox *C. difficile* Toxin Test at different time points. Spiked samples were tested after 0, 24, 48, 72, 96, and 100 hours of storage, and unspiked negative samples were tested after 0, 96, and 100 hours of storage.

Although there were trends of decreasing assay toxin signal average values and increasing neutralization ratio average values in spiked samples over time, the values were well within the cutoff threshold values to support a 72 hours stability claim when stored refrigerated at 2 – 8 °C.

6. Detection Limit and Analytical Reactivity:

Limit of Detection
The limit of detection (LoD) for Toxins A and B was determined by spiking known concentrations of purified Toxin A and B into negative pooled stool and testing with the

SensiTox *C. difficile* Toxin Test. Concentrations ranging from 1.5 to 3.5 ng/mL for Toxin A and 30 to 100 pg/mL for Toxin B were tested using three reagent lots across two analyzers. Twenty replicates per analyte dilution and per reagent lot were tested for a total of 60 replicates per analyte concentration. The LoD for each toxin was defined as the lowest concentration that generated a Detected result ≥ 95% of the time. The LoD for Toxin A was 3.5 ng/mL and the LoD for Toxin B was 50 pg/mL.

Analytical reactivity (Inclusivity)
A study was conducted to demonstrate reactivity of the SensiTox *C. difficile* Toxin Test with *C. difficile* A and B toxins sourced from a diverse collection of clinically relevant *C. difficile* strain ribotypes and toxinotypes (**Table 6**). Toxin A was purified from six ribotypes and tested at 15 ng/mL (4x LoD). Toxin B was purified from eight ribotypes and tested at 300 pg/mL (6x LoD). As a positive control, Toxins A and B were purified from the wildtype strain (ribotype 087), which was the standard toxin used throughout product development. All samples produced the expected positive result with the SensiTox *C. difficile* Toxin Test. One initial invalid result was observed in the study (1/49, 2.0% initial invalid rate), and this sample produced the valid expected result upon repeat testing (0% final invalid rate).

Table 6. *C. difficile* strain ribotypes source of purified toxin used in Inclusivity Study

Target Toxin	*C. difficile* Ribotype	*C. difficile* Toxinotype	Clinical Isolate
Toxin A	001	0	L1228
	002	0	D2177
	014	0	D1321
	027	III	1412
	078	V	312
	106	0	B5343
Toxin B	001	0	L1228
	002	0	D2177
	014	0	D1321
	017	VIII	NCTC 13569
	027	III	1412
	036	X	CCUG 20309
	078	V	312
	106	0	B5343

7. Assay Cut-Off:

Assay parameter thresholds were established based on the evaluation of negative stool specimens, contrived stool specimens spiked with *C. difficile* A and B toxins, and clinical specimens characterized by cellular cytotoxicity neutralization assay (CCNA) for *C. difficile* toxins. This included approximately 200 spiked specimens, 500 initial CCNA specimens, and an additional 300 CCNA specimens for confirmation.

8. Accuracy (Instrument):

Not applicable

9. Carry-Over:

A study was conducted to determine if carry-over contamination occurs within runs or between runs with the SensiTox *C. difficile* Toxin Test on the MultiPath Analyzer. The study used negative pooled stool samples and high positive samples contrived by spiking both Toxin A and B into negative stool at a concentration of 1.3 µg/mL (more than 370X LoD for Toxin A and 26,000X LoD for Toxin B). In total, 13 high positive and 13 negative samples were prepared in individual test cartridges and run on one MultiPath Analyzer using an alternating pattern within-run and between-run for a total of five runs. No evidence of carry-over effect was observed as all negative samples in the study produced the expected Not Detected result for both toxins.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable

2. Matrix Comparison:

Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

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. The study tested left-over, de-identified, unpreserved liquid or soft stool specimens sequentially collected from patients suspected of *C. difficile* infection. Stool specimens were stored up to 72 hours refrigerated at 2 – 8 °C prior to testing with the investigational device. Test performance was evaluated in comparison to the results of the cellular cytotoxicity neutralization assay which detects the presence of *C. difficile* toxin in fecal sample filtrates. Samples were stored and tested in accordance with the assay instructions and specifications.

Specimen inclusion and exclusion criteria were defined in the protocol. Specimens that met the study inclusion criteria and that did not meet any of the exclusion criteria were included in the analysis. Out of 1107 enrolled samples, 27 samples were excluded from the analysis due to sample processing or shipping errors and 20 samples were excluded due to storage outside of the sample stability timeframe. Results from a total of 1060 samples were available for analysis; 621 (59%) collected from females, 438 (41%) collected from males, and one collected from an individual whose gender was unknown. The age distribution is shown in **Table 7**.

Table 7. Age Distribution

Age	n	%
2-21	40	3.8%

Age	n	%
22-59	440	41.5%
>60	580	54.7%
Total	**1060**	**100%**

Of the 1060 samples, 14 samples (1.3%) required repeat testing with the SensiTox *C. difficile* Toxin Test due to initial invalid results, per the protocol. However, samples were not retested because they were either unavailable or exceeded the 72-hour sample stability timeframe. The remaining 1046 samples with valid results were included in the performance analysis.

The performance of the SensiTox *C. difficile* Toxin Test compared to the cellular cytotoxicity neutralization assay is shown in **Table 8**.

Table 8. Performance of the SensiTox *C. difficile* Toxin Test

		Cellular Cytotoxicity Neutralization Assay		
		Detected	**Not Detected**	**Total**
SensiTox *C. difficile* Toxin Test	**Detected**	87	41	128
	Not Detected	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%)		

2. Clinical Specificity:

   See Section VII.C.1.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

In the clinical study, a total of 1107 left-over, de-identified, unpreserved liquid or soft stool specimens sequentially collected from patients suspected of *C. difficile* infection were enrolled from three geographically diverse sites in the US. Of these specimens, 1046 provided valid test results for analysis of which 96 were positive by the cellular cytotoxicity neutralization assay comparator for an overall observed prevalence of 9.2% (96/1046). The overall percentage of positive results observed with the SensiTox *C. difficile* Toxin Test was 12.2% (128/1046).

F Other Supportive Instrument Performance Characteristics Data:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.