Spectrum Solutions, LLC
Katie Compton
Vice President of Quality Assurance and Regulatory Affairs
12248 South Lone Peak Pkwy, Ste 106
Draper, Utah 84020

February 17, 2023

Re: K223497
Trade/Device Name: Spectrum Saliva Collection Device
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial Nucleic Acid Storage And Stabilization Device
Regulatory Class: Class II
Product Code: QBD
Dated: November 18, 2022
Received: November 21, 2022

Dear Katie Compton:

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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*

Device Name
Saliva Collection

Indications for Use *(Describe)*
The Spectrum Solutions Saliva Collection Device is designed for use in the non-invasive collection, inactivation, and stabilization of viral nucleic acids for in vitro diagnostic testing of saliva samples. The device is intended to inactivate and stabilize human clinical saliva samples from the collection site to the laboratory at room temperature. The saliva sample is stabilized and suitable for use with legally marketed molecular diagnostic devices. The device is intended to be used by a health care provider for samples suspected of containing SARS-CoV-2.

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

Submitter's Name and Address:

Spectrum Solutions
12248 S. Lone Peak Parkway, Ste 106
Draper, UT 84020

Contact Name and Information:

Katie Compton
VP of Quality Assurance and Regulatory Affairs
Spectrum Solutions, LLC.
801- 569-0465 x215 (office)
801-719-8558 (cell)
Katie@spectrumsolution.com

Date prepared:

November 18, 2022

Device Information:

Trade/Proprietary Name:	Spectrum Solutions Saliva Collection Device
Common or Usual Name:	SDNA 1000
Classification Name:	Microbial nucleic acid storage and stabilization device
Classification Number:	Class II, 21 CFR 866.2950
Product Code:	QBD

Predicate Device:

510(k) Number	Device	Manufacturer
K202641	DNA/RNA Shield Collection Tube	ZYMO Research

Device Description:

The Spectrum Solutions Saliva Collection device consists of a plastic tube designed for the collection of human saliva samples, a funnel, a cap with a stem flare, and a fluid chamber containing Spectrum's inactivating media. Sample collection is conducted under the supervision of a Health care provide. The user deposits their saliva into the collection tube with the aid of the attached funnel, the user removes the funnel and replaces it with the cap. Upon twisting and closing the cap, the stabilizing solution is released into the tube and mixed with the saliva.

Indications for Use/Intended Use:

The Spectrum Solutions Saliva Collection Device is designed for use in the non-invasive collection, inactivation, and stabilization of viral nucleic acids for in vitro diagnostic testing of saliva samples. The device is intended to inactivate and stabilize human clinical saliva samples from the collection site to the laboratory at room temperature. The saliva sample is stabilized and suitable for use with legally marketed molecular diagnostic devices. The device is intended to be used by a health care provider for samples suspected of containing SARS-CoV-2.

Technological Characteristics:

The proposed device shares the same technological characteristics found in the predicate device and other cleared saliva collection devices on the market.

Feature:	Device: K223497	Predicate: K202641
Device Trade Name	Spectrum Solutions Saliva Collection Device	DNA/RNA Shield Collection Tube
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Spectrum Solutions Saliva Collection Device is designed for use in the non-invasive collection, inactivation, and stabilization of viral nucleic acids for in vitro diagnostic testing of saliva samples. The device is intended to inactivate and stabilize human clinical saliva samples from the collection site to the laboratory at room temperature. The saliva sample is stabilized and suitable for use with legally marketed molecular diagnostic devices. The device is intended to be used by a health care provider for samples suspected of containing SARS-CoV-2.	The DNA/RNA Shield collection tube is intended for the stabilization and inactivation of upper and lower respiratory human specimens suspected of containing SARS-CoV-2. These devices can be used for collection transport and storage of specimens at ambient temperatures (20-25°C). Specimens collected and stored in a DNA/RNA Shield™ collection tube are suitable for use with legally marketed molecular diagnostic devices.
Additive/Reagent	Nucleic Acid Stabilization solution	Same
Analyte	RNA from SARS-CoV-2	Same
Limit of Detection	250 GEC/ml (20 GEC/reaction)	Same
Specimen Stability	SARS-CoV-2 for 28 days at 20-25 °C	Same
Transport Media	Disrupt/lyses lipid membranes, inactivates enzymes, and stabilizes nucleic acids	Same
Material	Medical-grade polypropylene	Same
Sterility	Non-Sterile	Same
General Device Characteristic Differences		
Specimen Type	Saliva only	Upper, lower respiratory, and saliva
Device Material	Tube - Polypropylene Funnel Polypropylene Cap - Polypropylene & HDPE	Plastic Collection Tube pre-filled with DNA/RNA Shield transport media.

	Spectrum's Nucleic Acid Stabilization Solution	
Inactivation test	Greater than 4 Log viral reduction in 10 seconds	Greater than 2 log viral reduction in 30 minutes

The Spectrum Solutions Saliva Collection Device is substantially equivalent to the legally marketed predicate device. The Spectrum Solutions Saliva Collection Device has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device. Performance data demonstrates that the Spectrum Solutions Saliva Collection Device is as safe and effective.

Based on the technical characteristics and the results of the performance testing, the Spectrum Solutions Saliva Collection Device is substantially equivalent to the predicate.

Performance Data:

Detection Limit

a) Limit of Detection (LoD) testing was conducted to determine the lowest concentration of whole genome (Genome Equivalent Copies; GEC) that contains measurable nucleic acids that can be repeatedly recovered from the transport media with greater than 95% accuracy. LoD was obtained by spiking the Spectrum SDNA-1000 collection device containing negative matrix (saliva + preservative) with various concentrations of SARS-CoV-2 before RNA samples were extracted using the MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit performed with the KingFisher Flex Purification System and then amplifying using the TaqPath COVID-19 Combo Kit using the Applied Biosystems QuantStudio 5 (QS5) Fast Real-Time PCR System. The RNA extraction and RT-PCR kits contained an internal MS2 Phage control to monitor the integrity of nucleic acid extraction and RT-PCR for each specimen. Ct values and detection of virus were determined using the EUA IFU guidelines and the Applied Biosystems COVID-19 Interpretative Software v2.5.

   Acceptance criteria for RT-PCR reactions: For the COVID-19 TaqPath assay, Ct values <37 are considered positive for SARS-CoV-2. Ct values of 37 to <40 were considered inconclusive and those samples retested to determine SARS-CoV-2 status, as per the protocol Qualitative Detection of Nucleic Acid from SARS-CoV-2 using the COVID-19 TaqPath Combo Kit (JB-PRO-000105, v.2.1). Three gene targets in SARS-CoV-2 were subjected to amplification (ORF1ab, N gene, and S gene), with a sample considered positive if 2/3 of these gene targets were amplified.

b) Preliminary LoD testing was initially performed by spiking multiple concentrations of SARS-CoV-2 GEC into clinically negative matrix (saliva) to achieve final concentrations of 0, 10, 20, 50, 100, 250, and 500 GEC/reaction. Five samples of each of these contrived concentrations were tested with results shown below in Table 1.

Table 1. Preliminary LoD results (preliminary LoD highlighted) 5 samples tested/concentrations:

GEC/reaction	Orf1ab detection	ORF1a Mean Ct	N gene detection	N gene Mean Ct	S gene detection	S gene Mean Ct	SARS-CoV-2 positive result
0	0/5	ND	0/5	ND	0/5	ND	0/5
10	5/5	34.45	0/5	ND	0/5	ND	5/5
20	5/5	32.89	5/5	33.97	0/5	ND	5/5
50	5/5	31.81	5/5	31.90	5/5	33.45	5/5
100	5/5	30.43	5/5	30.30	5/5	31.66	5/5
250	5/5	29.44	5/5	29.06	5/5	30.13	5/5
500	5/5	29.05	5/5	28.84	5/5	29.67	5/5

The presumptive LoD based on the preliminary results was 20 GEC/reaction, but preliminary results with the 10 GEC/reaction showed that one of the three gene targets was amplified (ORF1ab). Therefore, it was possible that 15 GEC/reaction was a better LoD estimate. Therefore, both 15 and 20 GEC/reactions were each included in a set of 20 samples for confirmatory analysis of LoD (see Table 2). A positive result for a sample was defined as amplification of at least 2 of the 3 gene targets from SARS-CoV-2 (ORF1ab, N gene, S gene) per the IFU from the authorized device.

Confirmatory testing supported an LoD of 20 GEC/reaction with 20/20 replicates for amplification of ORF1ab and 20/20 replicates for N gene, which met the pre-defined criteria for RT-PCR reactions (greater than 95% accuracy for detecting 2/3 targets in samples). However, with 15 GEC/reaction, only 16/20 samples met the requirement of 2/3 targets amplified (80% accuracy), which fell below the pre-defined criteria. Therefore, 20 GEC/reaction is the established LoD.

Table 2. Confirmatory LoD results 20 samples tested/concentrations:

GEC/reaction	Orf1ab detection	ORF1a Mean Ct	N gene detection	N gene Mean Ct	S gene detection	S gene Mean Ct	SARS-CoV-2 positive result
15	20/20	33.92	16/20	35.29	0/20	ND	0/5
20	20/20	33.81	20/20	35.23	2/20	36.77	5/5

Ct values for each of the three amplified genes of the 20 replicates of the confirmatory tests for the 20 GEC/reaction concentration are shown in Table 3.

Table 3. Line data for confirmatory LoD results

	C_t Value		
Replicate	ORF1ab	N gene	S gene
1	36.14	34.83	
2	33.09	35.84	
3	33.35	36.09	
4	30.03	36.79	
5	34.50	34.48	
6	32.18	36.48	
7	34.60	34.79	36.66
8	33.55	34.42	
9	33.86	35.72	
10	34.71	36.63	
11	34.06	33.37	
12	34.24	36.01	36.87
13	33.85	34.47	37.61
14	32.80	35.45	37.83
15	34.17	34.02	
16	33.73	34.94	37.64
17	33.93	36.54	39.65
18	35.94	34.37	
19	33.15	35.12	
20	34.30	34.28	
AVG:	33.81	35.23	37.71
SD:	1.29	0.99	1.06

Note: The 69-70del mutation interferes with the detection of the S gene target by the TaqPath COVID-19 assay, which may have rendered the S gene target as not detected ("S gene target failure"). But due to the multi-target test design, the overall test performance of the TaqPath assay is not impacted.

In summary, the LoD testing at 250 GEC/ml (20 GEC/reaction) resulted in 20/20 replicates for automated extraction and amplification of SARS-CoV-2 RNA for identification by RT-PCR. This is the lowest concentration tested that resulted in > 95% accuracy of detection of contrived samples.

Sample Stability

Stability studies evaluated the stability of SARS-CoV-2 in the Spectrum inactivating media for up to 28 days. SARS-CoV-2 samples at 3xLoD (62.5 GEC/reaction; 1562.5 GEC/ml) were used to prepare contrived samples with saliva as the matrix from a single negative donor. Studies involved using two different device lots to collect two samples (for a total of 4 test samples) that were then stored at ambient temperature (20-25^{o}C) for increasing lengths of time. Aliquots of each contrived sample was tested for SARS-CoV-2 using the TaqPath COVID-19 assay at T=0 and on Days 1, 2, 3, 4, 5, 6, 7, 14, 21, and 28. Aliquots of samples were removed and stored at -20^{o}C at various times and then all aliquots (total of 44 samples) were tested as a single testing batch.

Acceptance criteria for stability study:

1) The TaqPath COVID-19 assay detects 3 targets (Orf1ab, N gene, and S gene). A sample is considered positive if at least 2 of the 3 targets are amplified with Ct values <37.
2) Stability is based upon a variance of no more than +/- 3 Ct for each target at given time point from T=0.

Results of stability testing are shown below in Tables 4 and 5.

Table 4. Ct average, standard deviation, and positive counts for all targets at all time points.

Time	Orf1ab Ct average	Orf1ab Ct SD	Orf1ab Positive Count	N gene Ct average	N gene Ct SD	N gene Positive Count	S gene Ct average	S gene Ct SD	S gene Positive Count
T0	33.1	0.98	4/4	31.7	0.32	4/4	32.8	0.34	4/4
D1	31.9	0.85	4/4	31.3	0.45	4/4	33.0	0.49	4/4
D2	32.4	0.33	4/4	31.4	0.33	4/4	33.8	0.61	4/4
D3	32.4	0.40	4/4	31.4	0.35	4/4	33.6	0.26	4/4
D4	32.7	1.23	4/4	31.6	0.46	4/4	34.0	1.74	4/4
D5	32.7	0.47	4/4	31.5	0.28	4/4	34.2	0.86	4/4
D6	32.7	0.43	4/4	31.6	0.29	4/4	33.4	0.47	3/4
D7	33.2	0.87	4/4	31.8	0.32	4/4	34.5	1.15	4/4
D14	33.7	0.84	4/4	32.1	0.19	4/4	33.8	NA	1/4
D21	34.4	0.79	4/4	33.1	0.68	4/4	NA	NA	0/4
D28	33.4	3.25	4/4	34.4	0.53	4/4	NA	NA	0/4

Table 5. Ct change for each target from T=0 (Day X minus T=0)

Time	Orf1ab Ct change from T0	N gene Ct change from T0	S gene Ct change from T0
T0	NA	NA	NA
D1	-1.25	-0.38	0.29
D2	-0.73	-0.34	1.04
D3	-0.72	-0.29	0.85
D4	-0.47	-0.15	1.19
D5	-0.43	-0.26	1.45
D6	-0.47	-0.10	0.69
D7	0.05	0.05	1.75
D14	0.52	0.38	1.04
D21	1.28	1.40	ND
D28	0.24	2.71	ND

43/44 of the samples tested positive for SARS-CoV-2 at all time points during initial testing. One Day 21 sampled failed to produce a conclusive result when first tested, but upon retesting the sample (per the TaqPath COVID-19 protocol) the sample gave a positive result. All samples gave expected internal control results (amplification of MS2 phage nucleic acid) to monitor the integrity of nucleic acid extractions and RT-PCR for each sample. There were minimal Ct changes over the 28 days of the experiment with the highest variance shown for N gene amplification, but at 2.71 it was within 3 Ct compared to T=0. The S gene target did show a decreased amount of amplification, but this is in agreement with 'S gene target failure (see table 3 above) and is negligible given the 2/3 gene amplification requirement for positive results.

Based upon the pre-defined acceptance criteria, these test results indicate samples are stable in the Spectrum inactivating media for up to 28 days.

Inactivation

An inactivation study was conducted to verify that the Spectrum SDNA-1000 collection device inactivates SARS-CoV-2 (eliminates its virucidal properties) as efficiently as the predicate device.

a) Viral inactivation testing of SARS-CoV-2 was conducted using a Virucidal Suspension Test (*In-Vitro* Time-Kill method). Starting with a concentration of a SARS-CoV-2 isolate (B.1.1.529 *Omicron* variant) of 3.2 X 10^6 $TCID_{50}$ (approximately 2.24 X 10^6 PFU), viral preparations were combined with various combinations of Spectrum inactivating media and/or neutralization fluid (for the inactivating media):

Virus Control = virus only *(to show virus produces cytopathic effect on tissue culture cells)*

Test = Spectrum's inactivating media + virus (**for 10 sec or for 60 min**) + neutralizer *(to show stabilizing solution inactivates virus)*

Neutralization Control = Spectrum's inactivating media + neutralizer + virus *(to show neutralizing solution eliminates virucidal activity of inactivating media)*

Neutralization Toxicity Control = virus + neutralizer *(to show neutralizer has no virucidal activity)*

Cytotoxicity Control = Spectrum's inactivating media + neutralizer *(to show solutions produce not cytotoxic effects)*

Cell Control = maintenance media only (*to show health of tissue culture cells*)

Following treatment of virus, 10-fold dilutions were made of each preparation and incubated with Vero E6 kidney cells that were grow to 80-90% confluency. After a one-hour incubation with the treatments listed above, cells were returned to culture conditions and incubated before cytopathic effects were determined visually with an inverted compound microscope.

Acceptance criteria for Virucidal Suspension Test: Results met the following acceptance criteria.

1) At least a 4 $\log_{10}$ of $TCID_{50}$ would be recovered from the virus control
2) At least a 3 $\log_{10}$ reduction in titer could be demonstrated beyond the cytotoxic level
3) Spectrum inactivating media was fully neutralized after the timed exposure such that the difference in virus titer for the Neutralization Control, Neutralization Toxicity Control, and Virus Control did not exceed 1.0 $\log_{10}$.

Three different lots of devices were tested for viricidal activity, with each test performed in two replicates per device. Plating of each replicate was performed four times. Results of testing for one device lot are summarized in Table 6.

Table 6. Viral Inactivation Summary

	10 sec.	60 min.	Dilution (- Log_{10})	Virus Control	Neutralization Control	Neutralizer Toxicity Control	Cytotoxicity Control
Rep 1	0000	0000	-3	++++	NT	NT	0000
Rep 2	0000	0000	-4	++++	++++	++++	0000
Rep 3	0000	0000	-5	++++	++++	++++	0000
Rep 4	0000	0000	-6	0+++	0+00	00+0	NT
Rep 5	0000	0000	-7	+000	0000	0+00	NT
Rep 6	0000	0000	-8	0000	0000	0000	NT
$TCID_{50}$ (Log_{10})	≤ 2.50			6.50	5.75	6.00	≤ 2.50
Log10 Reduction	≥ 4.00						
Average Log_{10} Reduction	≥ 4.00						
Percent Reduction	≥ 99.99%						
Average Percent Reduction	≥ 99.99%						

At the 1:10,000 dilution the virus is completely cytopathic with the host cells (*Virus control*) but completely inactivated at 10-second or 60-minute exposures to the inactivating media (*Test*). The virucidal action of the inactivating media was stopped by the neutralization solution (*Neutralization control*). The neutralization solution was shown to have no cytopathic effect on the cell mono layer or the virus (*Neutralizer Toxicity Control*). The inactivating media and the neutralizer combined did not produce any cytotoxic effects (*Cytotoxicity control*) on the cell mono layer.

Under the experimental conditions described above the Spectrum inactivating media inactivates SARS-CoV-2 by an average of $\geq$4.00 log_{10} (>99.99%) following a 10-second exposure and by an average of $\geq$4.00 log_{10} (>99.99%) following a 60-minute exposure. The Spectrum SDNA-1000 collection device with inactivating media showed no cytotoxicity of Vero6 cells when used at a 1:1000 dilution.

Conclusion:

The Spectrum Solutions Saliva Collection devices have the same intended purpose, indications and technological characteristics as the predicate.

The Spectrum Solutions Saliva Collection device does not raise different questions regarding safety and effectiveness as compared to predicate device. The proposed device is as safe, as effective, and performs as well as or better than the predicate device. The information submitted in this premarket notification supports a substantial equivalence decision.