Ningbo Dasky Life Science Co., Ltd.
Wilson Wong
Sales Manager
No. 6, Donggong 1st Road, Yinzhou District
Ningbo, Zhejiang 315000
China

August 8, 2022

Re: K211675
Trade/Device Name: Dasky Disposable Sampling Tube (Model name:VSM02)
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial nucleic acid storage and stabilization device
Regulatory Class: Class II
Product Code: QBD
Dated: May 25, 2021
Received: June 1, 2021

Dear Wilson Wong:

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,

Kristian Roth, Ph.D.
Deputy Director
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)*
K211675

Device Name
Dasky Disposable Sampling Tube (Model name: VSM02)

Indications for Use *(Describe)*
The Dasky Disposable Sampling Tube (Model name: VSM02) is intended for the stabilization, transportation and inactivation of infectious unprocessed nasopharyngeal specimen samples suspected of containing SARS-CoV-2. These devices can be used for collection transport and storage of specimens from the collection site to the laboratory. The specimens collected and stored in a Dasky Disposable Sampling Tube (Model name: VSM02) are suitable for use with compatible laboratory based molecular diagnostic devices.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: August 7,2022

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	NINGBO DASKY LIFE SCIENCE CO.,LTD.
Address:	No.6, Donggong 1st Road, Yinzhou District,Ningbo, Zhejiang, 315000 China
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2. Device Identification

510(K) number:	K211675
Trade/Device Name:	Dasky Disposable Sampling Tube (Model name: VSM02)
Models:	VSM02
Regulation Number:	21 CFR 866.2950
Regulation Description:	Microbial Nucleic Acid Storage And Stabilization Device
Regulation Class:	Class II
Panel:	Microbiology
Product Code:	QBD

3. Predicate Device

510(K) number:	K202641
Device Name:	DNA/RNA Shield Collection tube
Manufacturer:	Zymo Research
Regulation Description:	Microbial Nucleic Acid Storage And Stabilization Device
Regulation Number:	21 CFR 866.2950
Regulation Class:	Class II
Panel:	Microbiology
Product Code:	QBD

4. Device Description

The Dasky Disposable Sampling Tube (Model name: VSM02) consists of a plastic transport tube with medium which is supplied alone or in a kit with a nasopharyngeal (NP) swab, and an optional biosafety bag. The plastic transport tube contains 3 mL of the stabilization media. The components of the media are intended to inactivate SARS-CoV-2 virus, lyse the cells, disrupt/lyse the lipid membranes and denature proteins for storage of the specimen between 39 °F and 73 °F (4°C - 23°C). The media is sold in the following configurations.

- A plastic screw-cap tube filled with 3 mL of Dasky Disposable Sampling Tube media.
- A plastic screw-cap tube filled with 3 mL of Dasky Disposable Sampling Tube media and a NP nylon flocked swab for sample collection.

5. Indication for use

The Dasky Disposable Sampling Tube (Model name: VSM02) is intended for the stabilization, transportation and inactivation of infectious unprocessed nasopharyngeal specimen samples suspected of containing SARS-CoV-2. These devices can be used for collection transport and storage of specimens from the collection site to the laboratory. The specimens collected and stored in a Dasky Disposable Sampling Tube (Model name: VSM02) are suitable for use with compatible laboratory based molecular diagnostic devices.

6. Summary of the technological characteristics of the device compared to the Predicate Device

Compared to the predicate device, the subject device has the similar intended use, product design, and performance as the predicate device, the summarized comparison information is listed in following table 1:

Table 1: side by side comparison of subject device and predicate device

Device & Predicate Device(s):	Device: K211675	Predicate: K202641
Device Trade Name	Dasky Disposable Sampling Tube (Model name: VSM02)	DNA/RNA Shield Collection tube
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Dasky Disposable Sampling Tube (Model name: VSM02) is intended for the stabilization, transportation and inactivation of infectious unprocessed nasopharyngeal specimen samples suspected of containing SARS-CoV-2. These devices can be used for collection transport and storage of specimens from the collection site to the laboratory. The specimens collected and stored in a Dasky Disposable Sampling Tube (Model name: VSM02) are suitable for use with compatible laboratory based molecular diagnostic devices.	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.
Microorganism nucleic acids preserved	Same	SARS-CoV-2
Container	Same	Tube, plastic, screw cap vials
Medium Volume	3 mL	1 mL, 2 mL
Special conditions for use	Same	1. For in vitro diagnostic use only 2. For Prescription Use only
Sample source	Same	Human respiratory
General Device Characteristic Differences		
RNA stabilization at refrigeration	144 hours (4°C)	no refrigeration claims
RNA stabilization at ambient temperature	48 hours (23°C)	28 days
Specimen Type	Nasopharyngeal specimens for SARS-CoV-2.	Lower and Upper Respiratory Specimens for SARS-CoV-2.
Analyte	RNA	RNA and DNA
Shelf life	1 year	2 years

7. Performance Data

1) Limit of detection

The detection limit of SARS-CoV-2 nucleic acid (RNA) in 3 mL media in the Dasky Disposable Sampling Tube (Model name: VSM02) was determined. The detection limit concentration was verified to ensure that SARS-CoV-2 RNA could be repeatedly recovered from the disposable sample tube at the lowest detection concentration with an accuracy greater than 95%. LoD testing was conducted by spiking multiple volume of SARS-CoV-2 virus with a titer of 1x 10^5 GCE/mL into the clinical NP swab specimen, collected from healthy individuals who tested negative for SARS-CoV-2 virus, and then using the NP swab to transfer the sample into 3 mL of media in the Dasky Disposable Sampling Tube (Model name: VSM02) to achieve final concentrations of 63 GCE/mL, 70 GCE/mL, 10^2 GCE/mL, 3x 10^2 GCE/mL 10^3 GCE/mL, and 10^4 GCE/mL, for each of the 20 tubes/lot for three lot.

Purified RNA was extracted from 200 µL samples by using MagMAX Viral/Pathogen Nucleic Acid Isolation Kit manufactured by Thermo Fisher Scientific. RT-PCR was performed on the Applied Biosystems 7500 Quantitative Real-time PCR System and TaqPath COVID-19 Combo Kit manufactured by Thermo Fisher Scientific.

~78% detection (viral targets C_t values are <37) of the SARS-CoV-2 RNA were observed in samples at 63 GCE/mL (13/60 replicates). The detection of the SARS-CoV-2 RNA at all other higher concentrations: 70 GCE/mL, 10^2 GCE/mL, 3x 10^2 GCE/mL 10^3 GCE/mL, and 10^4 GCE/mL resulted in 20/20 replicates for each of the three lots (Lot 21060832-02, Lot 21060732-02 and Lot 21061132-02). The LoD testing results are summarized in Table 2:

Table 2. LoD testing

GCE/mL	Total #	Positive #	Mean C_t		
			ORF1ab	N gene	S gene
10^4	60	60	20.94	21.08	21.04
10^3	60	60	24.23	23.99	24.12
3x 10^2	60	60	26.70	26.95	26.93
10^2	60	60	29.95	30.04	30.29
70	**60**	**60**	**32.84**	**32.82**	**33.94**
63	60	47	36.13	36.04	35.89

In summary, the LoD testing at 70 GCE/mL resulted in 60/60 replicates for NP swabs, which meet the pre-defined acceptance criteria for NP swabs.

2) Specimen Stability

The specimen stability study was conducted by spiking 4.5 µL of SARS-CoV-2 virus at 1x 10^5 GCE/mL into the clinical NP swab specimen collected from individuals who tested negative for SARS-CoV-2 virus, then using the NP swab to transfer the virus sample into the Dasky Disposable Sampling Tube (Model name: VSM02) containing 3 mL media to achieve the final concentration of the samples at 150 GCE/mL (2.1x LoD).

Three Dasky Disposable Sampling Tube (Model name: VSM02) of each lot (Lot 20100732-01, Lot 21060732-02 and Lot 21121032-01) were tested by RT-PCR and served as T_0; The measured C_t values for the samples stored at 23°C for at least 48 hours and 4°C for at least 144 hours were defined as $T_{23->48}$ and $T_{4->144}$, respectively. Purified RNA was extracted from 200 µL samples by MagMAX Viral/Pathogen Nucleic Acid Isolation Kit manufactured by Thermo Scientific. RT-PCR was performed on the ABI7500 using the EUA-authorized TaqPath COVID-19 Combo kit of Thermo Scientific. The results for the specimen stability study are summarized in Table 3.

Table 3. Specimen Stability

Lot No.	Storage condition	Replicate	C_t			Interpretation	% Positive
			ORF1ab	N gene	S gene		
20100732-01	T_0	1	28.6	28.7	28.4	Positive	100%
		2	29.7	29.6	29.2	Positive	
		3	28.3	28.2	28.1	Positive	
	$T_{23->48}$	1	30.9	30.1	30.3	Positive	
		2	30.5	30.9	29.8	Positive	
		3	29.9	29.3	29.9	Positive	
	$T_{4->144}$	1	29.0	29.4	29.0	Positive	
		2	30.7	30.1	29.5	Positive	
		3	29.8	30.1	30.9	Positive	
21060732-02	T_0	1	29.1	29.2	28.8	Positive	
		2	29.0	30.5	29.8	Positive	
		3	28.3	28.7	29.6	Positive	
	$T_{23->48}$	1	29.2	28.9	29.8	Positive	
		2	29.4	29.8	30.5	Positive	
		3	28.5	29.6	29.9	Positive	
	$T_{4->144}$	1	29.8	29.5	29.0	Positive	

		2	29.2	29.0	29.5	Positive	
		3	30.2	30.5	30.9	Positive	
21121032-01	T_0	1	28.1	28.9	29.7	Positive	
		2	29.8	28.7	28.3	Positive	
		3	28.1	29.5	29.8	Positive	
	$T_{23->48}$	1	30.0	30.9	29.7	Positive	
		2	29.3	29.8	28.7	Positive	
		3	29.0	28.3	29.5	Positive	
	$T_{4->144}$	1	29.4	29.0	29.3	Positive	
		2	29.1	29.4	29.6	Positive	
		3	29.4	29.3	29.1	Positive	

The deviation between the initial C_t measurement value and the C_t measurement value of samples stored at either 23°C for a minimum of 48 hours or 4°C for a minimum of 144 hours is less than 2 C_t. The results demonstrated acceptable RNA stabilization at 23°C for 48 hours or 4°C for 144 hours.

3) Inactivation

Three lots of Dasky Disposable Sampling Tube (Model name: VSM02) were used for the inactivation assessment. In the experimental group, 30 µL SARS-CoV-2 virus at 1×10^5 Genomic Copy Equivalents (GCE)/mL (determined by real-time qPCR) was added to clinical nasopharyngeal (NP) swab specimens, collected from 9 healthy individuals who tested negative for SARS CoV-2 virus, then using the NP swab to transfer the virus sample into the Dasky Disposable Sampling Tube (Model name: VSM02), containing 3 mL media to achieve the final concentration 10^3 GCE/mL. In the control group, 30 µL SARS-CoV-2 virus with a titer of 1×10^5 GCE/mL was added to clinical NP swab specimens, collected from healthy individuals who tested negative for SARS CoV-2 virus, then using the NP swab to transfer the virus sample into 3 mL PBS (phosphoric acid buffer). The experimental group and the control group were incubated at room temperature for five (5) minutes. After 5 minutes, the samples of the experimental group and the control group were diluted 1:1000 with ultrapure water; 30 µL of diluted samples from the experimental group and control group were incubated with Vero-E6 cells (the cells were implanted in 96-well plates one day in advance, each well includes 30 µL Vero-E6 cells at $1x\ 10^5$ GCE/mL), respectively. After 4 days of infection, the morphology of the cells was observed under an electron microscope to determine the cytological changes. By observing the cell morphology of the infected Vero-E6 cells, it was found that the virus in the control group could infect Vero-E6 cells. In the experimental group, the virus was inactivated and was no longer able to infect Vero-E6 cells. The intact morphology of the cells

could be observed under the microscope. The results for the inactivation assessment are summarized in Table 4.

Table 4. Virus inactivation assessment

Sample type (SARS-CoV-2 virus at 1x 10^3 GCE/mL)	Test number	LOT No.		
		20100732-01	21060732-02	21121032-01
		Inactivation results		
Experimental group	1#	uninfected	uninfected	uninfected
	2#	uninfected	uninfected	uninfected
	3#	uninfected	uninfected	uninfected
Control group	1#	infected		

In the inactivation assessment, three batches of media in the Dasky Disposable Sampling Tube (Model name: VSM02) were tested. For the SARS-CoV-2 virus at a titer of 10^3 GCE/mL, it can be 100% inactivated at a minimum of 5 minutes in the Dasky Disposable Sampling Tube (Model name: VSM02).

4) Shelf life

The Shelf-life for the Dasky Disposable Sampling Tube (Model name: VSM02) is 1 year after the date of manufacture. The stability of the Dasky Disposable Sampling Tube (Model name: VSM02) was performed using Realtime stability study on a total of 9 samples (3 lots). The item appearance inspection, pH detection, RT-PCR test, virus inactivation efficiency detection and Limit of detection are considered as the factor of evaluation.

8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device (K202641).