December 14, 2020

Zymo Research
Julie Ogi
Regulatory Officer
17062 Murphy Ave.
Irvine, California 92614

Re: K202641
Trade/Device Name: DNA/RNA Shield Collection Tube
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial Nucleic Acid Storage and Stabilization Device
Regulatory Class: Class II
Product Code: QBD
Dated: September 8, 2020
Received: September 11, 2020

Dear Julie Ogi:

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.
Branch Chief
Bacterial Respiratory and Medical Countermeasures 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202641

Device Name

DNA/RNA Shield Collection Tube

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Applicant	Zymo Research 17062 Murphy Ave. Irvine, CA 92614 USA
Establishment Registration No.	Pending / User Fees Paid
Contact Person	Julie Ogi Regulatory Officer Phone (949) 679-1190 Fax (949) 266-9452 e-mail jogi@zymoresearch.com
Summary Date	September 8, 2020
Proprietary Name	DNA/RNA Shield™ collection tube
Common name	DNA/RNA Shield
Device	Transport device for the stabilization of microbial nucleic acids
Product Codes / Regulation Numbers	QBD - Transport device for the stabilization of microbial nucleic acids / 21 CRF 866.2950
Classification	Class II
Review Panel	Microbiology 83
Predicate Devices	PrimeStore MTM (DEN170029)

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Intended Use

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.

Device Description

The DNA/RNA Shield™ collection tube and reagent consist of a tube pre-filled with DNA/RNA Shield™ transport media. DNA/RNA Shield™ is a transport media that ensures stability of SARS-CoV-2 RNA during sample transport/storage at ambient temperatures and is intended to inactivate SARS-CoV-2, effectively lyses cells from collected upper and lower respiratory biological specimens. The DNA/RNA Shield™ transport media may be kitted with a swab, sputum collection kit or as a tube alone.

Comparison to Predicate Device

Similarities		
Item	Predicate Device: PrimeStore MTM (DEN170029)	Proposed Device: DNA/RNA Shield™ collection tube and reagent
Intended Use	PrimeStore MTM is a device intended for the stabilization, transportation and inactivation of infectious unprocessed nasal washes suspected of containing Influenza A (Flu A) virus RNA or unprocessed sputum samples suspected of containing *Mycobacterium* tuberculosis (MTB) DNA from human samples. Transport device can transport and store specimens between 36-77 °F (2-25 °C).	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.
Special conditions for use	1. For *in vitro* diagnostic use only 2. For prescription use only	1. For *in vitro* diagnostic use only 2. For prescription use only
DNA/RNA stabilization at ambient temperature	28 days: MTB 8 days: Flu A	≤28 days sputum and OP
Sample source	Human respiratory	Human respiratory

Differences		
Item	Predicate Device: PrimeStore MTM(DEN170029)	Proposed Device: DNA/RNA Shield™ collection tube and reagent
RNA stabilization at refrigeration	≤8 days flu ≤36 days MTB	no refrigeration claims
Analyte	DNA, RNA	RNA
Sample collection	Nasal wash suspected of containing Influenza A virus. Sputum samples suspected of containing MTB.	Lower and Upper Respiratory Specimens for SARS-CoV-2.

Performance data:

Inactivation

An inactivation study was conducted to verify that DNA/RNA Shield inactivates SARS-CoV-2 virus as efficiently as other legally marketed devices.

High concentrations of SARS-CoV-2 virus ($9x10^5$ PFU) were inoculated into DNA/RNA Shield. The viability of the virus was measured after 30 min in DNA/RNA Shield medium by inoculating aliquots onto veroE6 cells, incubating for two days and measuring the cytopathic effect (CPE).

The results for the inactivation study indicated a CPE of < 3.0 log reduction because of the DNA/RNA Shield media alone cause cell toxicity. The media and virus confirmed > 2.0 log reduction in viral titer after a 30 min exposure and demonstrates equivalent performance of DNA/RNA Shield with PrimeStore MTM™ for inactivation.

Limit of detection

An analytical sensitivity study was conducted to determine the SARS-CoV-2 Limit of Detection (LoD) obtained by DNA/RNA Shield in combination with the *Quick* SARS-CoV-2 rRT-PCR Kit. The RNA was spiked into DNA/RNA Shield medium then samples were extracted using the *Quick*-DNA/RNA Viral MagBead kit performed on the KingFisher™ Flex Purification System and then amplified using the Authorized *Quick* SARS-CoV-2 rRT-PCR Kit. The DNA/RNA Shield reached an LoD of 250 GEC/mL (15 GEC/reaction) for sputum and oral swab.

Specimen Stability

A stability study was designed to demonstrate that SARS-CoV-2 RNA from sputum and oral swab was preserved and stabilized in DNA/RNA Shield media. The stability studies used contrived specimens with sample matrices and SARS-CoV-2 RNA spiked into DNA/RNA Shield. The specimens were then amplified using the *Quick* SARS-CoV-2 rRT-PCR Kit. The results of SARS-CoV-2 RNA stability study confirmed that RNA stabilized in DNA/RNA Shield met the acceptance criteria of +/- 3.0 Ct after 4 weeks storage at 20 - 25 °C. This study demonstrates equivalent performance of DNA/RNA Shield with the legally marketed predicate device.

Conclusion:

Based on the above, Zymo Research believes that the DNA/RNA Shield collection tube is substantially equivalent to the legally marketed predicate device for the inactivation, LoD and stabilization of specimens containing SARS-CoV-2 for collection, stabilization and recovery. No new issues of safety or effectiveness were found for the DNA/RNA Shield collection tube.