

May 27, 2025

Puritan Medical Products LLC  
Mehdi Karamchi  
V.P. of Scientific Affairs  
31 School Street PO Box 149  
Gulford, Maine 04443-0149

Re: K242820

Trade/Device Name: Puritan PurSafe Plus Collection and Transport System  
Regulation Number: 21 CFR 866.2950  
Regulation Name: Microbial Nucleic Acid Storage And Stabilization Device  
Regulatory Class: Class II  
Product Code: QBD  
Dated: April 25, 2025  
Received: April 25, 2025

Dear Mehdi Karamchi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Noel J. Gerald -S**

Noel J. Gerald, Ph.D.  
Deputy Division Director  
Division of Microbiology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K242820

Device Name  
Puritan PurSafe Plus Collection and Transport System

### Indications for Use (Describe)

Puritan PurSafe Plus Collection and Transport System is an enclosed system intended for the collection, inactivation, and preservation of human upper respiratory specimens suspected of containing SARS-CoV-2. Puritan PurSafe Plus Collection and Transport System can be used for collection, transport, and storage of specimens at 2-4°C and 25-30°C. Specimens collected and stored in the PurSafe Plus Collection and Transport System 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary

### Puritan® PurSafe® Plus Collection and Transport System

### 510(k) Submission # K242820

#### 1.0 Sponsor

Puritan Medical Products LLC

31 School St., Guilford, ME

04443

Contact: Mehdi Karamchi

Telephone Number: 207-876-3311

Fax Number: 207-876-2680

Date: September 16, 2024

#### 2.0 Device Name

Classification Name: Microbial nucleic acid storage and stabilization device

Common Name: Puritan® PurSafe® Plus Collection and Transport System

Proprietary Name: Puritan® PurSafe® Plus Collection and Transport System

#### 3.0 Regulatory Information

A. Regulatory Section: 21 CFR 866.2950

B. Classification: Class II

C. Product Code: QBD

D. Panel: Microbiology

#### 4.0 Predicate Device

Zymo Research DNA/RNA Shield Collection Tube

510(k) Number: K202641

## **5.0 Device Description**

Puritan PurSafe Plus Collection and Transport System is comprised of a peel pouch containing a sterile polyester flock swab applicator for collecting clinical specimens and a polypropylene vial containing 1mL PurSafe Plus buffer.

PurSafe Plus MK buffer ensures stability of Sars Cov-2 during sample transport/storage at refrigerated to ambient temperature (4-30°C) and is intended to inactivate Sars Cov-2.

## **6.0 Intended Use**

Puritan PurSafe Plus Collection and Transport System is an enclosed system intended for the collection, inactivation, and preservation of human upper respiratory specimens suspected of containing SARS-CoV-2. Puritan PurSafe Plus Collection and Transport System can be used for collection, transport, and storage of specimens at 2-4°C and 25-30°C. Specimens collected and stored in the PurSafe Plus Collection and Transport System are suitable for use with legally marketed molecular diagnostic devices.

## **7.0 Test Device and Predicate Device Comparison**

Item	Test Device	Predicate  Zymo Research DNA/RNA Shield Collection Tube  510(k) Number: K202641
Intended USE	Puritan PurSafe Plus Collection and Transport System is an enclosed system intended for the collection, inactivation, and preservation of human upper respiratory specimens suspected of containing SARS-CoV-2. Puritan PurSafe Plus Collection and Transport System can be used for collection, transport, and storage of specimens at 2-4°C and 25-30°C. Specimens collected and stored in the PurSafe Plus Collection and Transport System are suitable for use with legally marketed 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.
Single-use Device	Yes	Same
Medium Formulation	Inactivation Buffer Salts pH Buffering agent Molecular Grade Water	Inactivation buffer Salts pH Buffer Water
pH	8.3 ± 0.2	5.0-7.0
Storage Temperature	4-30°C (refrigerated and room temperature)	20-25°C (ambient temperature)
Container	Polypropylene conical bottom vial	Same

Product Configuration	Medium in vial & cap System including Medium and swab in peel pouch option.	Same
Swab Shaft	Plastic	Same
Swab Tip	Flock Swab	Same
Shelf Life	24 months	24 months
Analyte	RNA	RNA

## 8.0 Performance Characteristics

### **Limit of Detection (LOD)**

Limit of Detection studies were carried out to assess the minimum concentration of viral RNAs from Sars-CoV-2 detectable via the Cepheid GeneXpert® IV system using the 4 Plus TEST KIT, (COV-2/FLU/RSV PLUS X PERT XPRESS) (Cat #: XP3COV2/FLU/RSV-10). The stated limit of detection for the Cepheid Xpert Xpress Cov-2/Flu/RSV is 64 copies/mL for nasal swab specimens (XP3COV2/FLURSV-1).

The LOD studies were performed with heat-inactivated Sars-Cov-2 (BEI Resources; ATCC # VR-1986HK, Lot # 70037781) at a stated initial concentration of  $4.2 \times 10^5$  genome copies per  $\mu\text{L}$ . LOD assays were carried out on one lot of Puritan PurSafe Plus Collection and Transport System (Lot 240312, expiration 3/12/2026) and one lot of the Zymo product (DNA/RNA Shield™ R1107 Lot 236390 expiration 5/1/2026).

Performance of both products were evaluated in clinically negative (confirmed by ddPCR) nasal matrix (Lee Biosolutions, Maryland Heights, MO). The LOD was assessed for Sars-CoV-2 viral RNA for estimated final concentrations of 256, 128, 64, 32, 16 and 0 genome copies/mL. For both the PurSafe lot and Zymo, two replicates were quantified at each concentration (N=24; 6 concentrations x 2 replicates x two lots). Additionally, to assess possible effects of the Puritan PurSafe Plus alone, detection was assessed in the nasal matrix alone and compared against nasal matrix with Puritan PurSafe Plus using droplet digital PCR.

For the Puritan PurSafe Plus as well as for the Zymo lot LOD studies indicated positive detection of viral RNA using the Cepheid GeneXpert® IV system to an estimated concentration of 64 genome copies/mL. This is the stated limit of detection for the Cepheid Xpert Xpress Cov-2/Flu/RSV system. This study indicates that the use of Puritan PurSafe has no adverse effect on the stated detection limits of the Cepheid instrument. Additionally, quantitative droplet digital PCR showed no significant loss of detection for samples stored in Nasal + PurSafe Plus compared to just nasal matrix alone. There were no significant differences in Sars-CoV-2 RNA

positive detection among PurSafe lots and Zymo. Additionally, 20 replicates at the LOD concentration of 64 genome copies/mL carried out over six days indicated positive detection for all replicates. Less than two Ct values separated the highest (37.6) and lowest (36.0) values.

### **Stability Studies**

The objective of this study was to assess the ability of the PurSafe Plus Collection and Transport System to store viral RNAs from Sars-CoV-2 for up to 28 days at ideal and relatively high (4°C and 30°C) temperatures. As was done for the LOD studies, heat inactivated Sars-CoV-2 (BEI Resources; ATCC # VR-1986HK, Lot # 70037781) were spiked into the confirmed clinically negative Nasal matrix (Lee Biosolutions, Maryland Heights, MO) with the transport media to achieve an estimated final concentrations 2-3 times the LOD (100 genome copies/mL). Three Puritan lots were evaluated; “new” product (Lot 240312, expiration 3/12/2026), “mid” product (Lot 230207, expiration 2/7/2025) and an “expired” product (Lot 221109, expiration 9/11/2024) and one lot of the Zymo product (DNA/RNA Shield™ R1107 Lot 236390 expiration 5/1/2026). RNA detection for each lot (4), time point (5) and incubation temperature (2) was assessed with two replicates (N=72) using a Cepheid GeneXpert® IV system using the 4 Plus TEST KIT, (COV-2/FLU/RSV PLUS X PERT XPRESS).

For all three Puritan lots and the Zymo lot in clinically negative matrices all samples yielded sufficient RNA for positive detection using the Cepheid GeneXpert® IV system. For all samples stored at 4°C and 30°C for up to 28 days showed no significant loss in the ability to positively detect Sars-CoV-2 in the Cepheid GeneXpert® IV system. Mean Ct values for all samples across all time points and temperatures were less 3 Ct units from baseline (Time = 0) values. All Puritan lots were equivalent to the Zymo product in preservation of Sars-CoV-2 RNA for up to 28 days at both 4°C and 30°C.

### **Inactivation**

Uninfected VeroE6 cells were exposed to the Puritan PurSafe Plus Buffer to assess possible cytotoxicity. Cytotoxicity with the PurSafe Plus buffer alone was observed at a dilution of 1/10 but the 1/60<sup>th</sup> dilution had healthy cells. For subsequent inactivation studies, a 1:60 dilution was used for the Puritan PurSafe Plus Collection and Transport System. SARS-CoV-2 virus was inactivated after exposure to the 3 different lots of Puritan PurSafe Plus buffer (at 1:0 dilution) after a minimum of 1 minute of exposure.

Based upon statistical analyses we conclude that the Puritan PurSafe Plus Collection and Transport System performed equally to the commercial product, Zymo DNA/RNA Shield™.

## **9.0 Conclusion**

The conclusions drawn from the nonclinical tests demonstrate the device is as safe and effective as the legally marketed device identified above.