



July 29, 2016

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

PURITAN MEDICAL PRODUCTS LLC  
MEHDI KARAMCHI  
VICE PRESIDENT OF SCIENTIFIC AFFAIRS  
31 SCHOOL STREET  
P.O. BOX 149  
GUILFORD ME 04443-0149

Re: K160082

Trade/Device Name: Puritan Opti-Tranz Cary-Blair Collection and Transport System  
Regulation Number: 21 CFR 866.2390  
Regulation Name: Transport culture medium  
Regulatory Class: I  
Product Code: JSM, LIO, JTW  
Dated: July 14, 2016  
Received: July 18, 2016

Dear Mr. 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 (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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Ribhi Shawar -S**

For Uwe Scherf, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

k160082

Device Name

Puritan Opti-Tranz Cary-Blair Collection and Transport System

Indications for Use (Describe)

Puritan Opti-Tranz Cary-Blair Collection and Transport System is intended for use in the collection and transport of clinical fecal and rectal swab specimens to preserve the viability of enteric bacteria during transport from the collection site to the testing laboratory for bacteriological examination and culture.

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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## 510(k) Summary

### Puritan® Opti-Tranz™ Cary-Blair Collection and Transport System

#### 5.1 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: May 25, 2016

#### 5.2 Device Name

Classification Name: Transport Culture Medium

Common Name: Specimen Collection and Transport System

Proprietary Name: Puritan® Opti-Tranz™ Cary-Blair Collection and Transport System

#### 5.3 Regulatory Information

A. Regulatory Section: 21 CFR 866.2390

B. Classification: Class I

C. Product Code: LIO, JSM, JTW

D. Panel: Microbiology (83)

#### 5.4 Predicate Device

Copan Venturi Transystem Cary-Blair Medium product (132C)

510K Number: K946286

## **5.5 Device Description**

Puritan Opti-Tranz Cary-Blair Collection and Transport System is comprised of a sterile peel pouch containing a rayon tipped swab applicator for collecting specimens and a polypropylene tube containing 5 ml of Cary-Blair medium.

Cary-Blair medium is a nonnutritive balanced salt solution containing disodium phosphate to provide buffering capability, sodium chloride and calcium chloride to provide essential ions that help maintain osmotic balance. Agar is a solidifying agent and gives a semisolid texture to the medium. Sodium thioglycollate provides a reduced environment. It is recommended for maintaining the viability of enteric bacteria during the transport to the laboratory.

## **5.6 Intended Use**

Puritan Opti-Tranz Cary-Blair Collection and Transport System is intended for use in the collection and transport of clinical fecal and rectal swab specimens to preserve the viability of enteric bacteria during transport from the collection site to the testing laboratory for bacteriological examination and culture.

## **5.7 Indication(s) For Use**

Puritan Opti-Tranz Cary-Blair Collection and Transport System is intended for use in the collection and transport of clinical fecal and rectal swab specimens to preserve the viability of enteric bacteria during transport from the collection site to the testing laboratory for bacteriological examination and culture.

## **5.8. Substantial Equivalence statement**

Puritan Opti-Tranz Cary-Blair Collection and Transport System is similar in design, manufacturing and intended usage to the predicate device. Both the Puritan and the predicate device are single-use devices intended for collection and transport of clinical specimens containing enteric bacteria from the patient site to the testing laboratory for bacteriological examination and culture.

<b>Puritan and Predicate Device Comparision</b>		
<b>Item</b>	<b>Puritan Test Device</b>	<b>Predicate</b>
Intended USE	Puritan Opti-Tranz Cary-Blair Collection and Transport System is a sterile ready-to- use system intended for collection and transport of clinical fecal and rectal swab specimens to preserve the viability of enteric bacteria during transport from the collection site to the testing laboratory for bacteriological examination and culture.	Copan Venturi Transystem Cary-Blair Medium product (132C) is a sterile ready-to-use system intended for the safe collection, transport, and preservation of clinical specimens for bacteriological examination. Product 132C is supplied with a plastic applicator swab. The Venturi Transystem with Cary-Blair Transport Medium is recommended for the collection and transport of fecal and rectal swab samples for the investigation of enteric pathogenic bacteria.
Single-use Device	Yes	Same
Medium Formulation	Sodium chloride Disodium phosphate Sodium thioglycollate Calcium chloride Agar Water	Same
pH	6.90-7.50	8.4 ± 0.2
Storage Temperature	2-25°C (refrigerated and room temperature)	Same
Container	Plastic round bottom tube	Same
Product Configuration	Medium in tubes & Plug  System including Medium and	Same

	swab in peel pouch option.	
Swab Shaft	Plastic	Same
Swab Tip	Rayon tipped swab	Same
Shelf Life	20 months	24 months

## 5.9 Recovery Testing

To determine the ability of the Puritan Opti-Tranz Cary-Blair Collection and Transport System to maintain viability of different strains of enteric bacteria, known inoculum of clinically significant ATCC type culture microorganisms were inoculated into the Puritan Opti-Tranz Cary-Blair Collection and Transport medium and compared to the predicate device following Clinical and Laboratory Standards Institute (CLSI) M40-A2 guidelines. No notable differences in recovery were detected between the Puritan Opti-Tranz Cary-Blair Collection and Transport System and the predicate device.

Recovery was also evaluated using three representative challenge organisms to demonstrate that the performance of the Puritan Opti-Tranz Cary-Blair Collection and Transport medium is not adversely affected by fecal material. It was determined that clinical fecal material does not notably alter the recovery of the challenge organisms from the Puritan Opti-Tranz Cary-Blair Collection and Transport System.

## 5.10 Stability Testing

Stability tests were performed on Puritan Opti-Tranz Cary-Blair Collection and Transport System to verify the ability of the aged products to maintain microbial recovery up to the expiry date.

## 5.11 pH Stability

The pH of the test device was measured at predetermined time intervals for up to 20 months after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan Opti-Tranz Cary-Blair Collection and Transport System. All samples tested were found to maintain pH within the specified range.

## 5.12 Cytotoxicity

Cytotoxicity testing was conducted to evaluate the glue, shaft and the rayon tipped swabs for potential cytotoxicity effect following ISO Elution Method-1X MEM Extract. No evidence of cytotoxicity was detected.

### **5.13 Sterilization**

Puritan Opti-Tranz Cary-Blair Collection and Transport System is sterilized by gamma irradiation and validated following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products Radiation guidelines.

### **5.14 Conclusion**

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