



November 26, 2025

Medical Wire & Equipment Company (Bath) Ltd
Shedden Douglas
Technical Director
Unit 29 Potley Lane
Corsham, Wiltshire SN13 9RT
United Kingdom

Re: K242976

Trade/Device Name: Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and
Transport Device

Regulation Number: 21 CFR 866.2390

Regulation Name: Transport Culture Medium

Regulatory Class: Class I, reserved

Product Code: JSM

Dated: April 3, 2025

Received: April 3, 2025

Dear Shedden Douglas:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KIMBERLY Digitally signed
by KIMBERLY
ANDERSON -S *for*
N -S ANDERSON -S
Date: 2025.11.26
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Ribhi Shawar, Ph.D. (ABMM)

Chief

General Bacteriology and Antimicrobial Susceptibility
Branch

Division of Microbiology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure



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Chief

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Enclosure

510(k) Summary for Medical Wire Fecal Transwab® Liquid Cary Blair Collection and Transport Device

The assigned 510(k) number is: K242976

1. Submitter

Medical Wire & Equipment Co. (Bath) Ltd.,
Corsham,
Wiltshire
SN13 9RT
United Kingdom

Contact Person: Douglas Shedden
Telephone: +441225 810361

2. Device Name

Proprietary Name	Medical Wire Fecal Transwab® Liquid Cary Blair Medium Collection and Transport Device
Common/Usual Name	Transport Culture Medium Devices
Classification Name	21 CFR 866.2390 Transport Culture Medium Devices
Product Code	JSM

3. Device Description

Each Fecal Transwab® Liquid Cary Blair Medium Collection and Transport Device comprises a sterile peel pouch containing a plastic screw-cap self standing tube with conical shaped bottom filled with 2 ml of Liquid Cary Blair transport medium and a specimen collection swab with a polyurethane foam coated tip. After sampling the swab applicator is placed in the tube where the bud is bathed in the liquid medium. The swab shaft is broken to allow the swab to fit in the tube, with the screw-cap being replaced.

Fecal Transwab can also be supplied as a medium only device without a swab, in which case the specimen can be inoculated into the medium using a sterile swab, or scoop, or inoculating loop.

The Liquid Cary Blair transport medium is a maintenance medium comprising inorganic phosphate buffer, calcium chloride and sodium chloride with a reduced environment due to the presence of sodium thioglycollate. The medium is designed to maintain the viability without overgrowth of enteric bacteria during transit to the testing laboratory.

The foam-tipped collection swab provided with the Medical Wire Fecal Transwab® Collection and Transport System has a plastic shaft with a defined breakpoint site. A bold red marker line indicates the limit of insertion if the swab is used to take a rectal specimen.

4. Predicate Device: Copan Italia S.p.A., Copan FecalSwab Collection, Transport and Preservation System (K142094).

Device & Predicate Device(s):	<u>Device: K242976</u>	<u>Predicate: K142094</u>
Device Trade Name	Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device	Copan FecalSwab Collection, Transport and Preservation System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device is intended to preserve the viability and infectivity of fecal specimens after their collection and during transport from the collection site to the testing laboratory. The product can be used to collect stool specimen directly from the patient, using the swab as a rectal swab. Alternatively, the swab can be used to take material from a previously collected stool specimen. Fecal Transwab specimens are processed using standard clinical laboratory operating procedures for microbiological specimens.	The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.
Specimen Type	Stool specimen, rectal specimen	Same

Microorganisms supported	Enteric pathogenic bacteria	Same
Tube configuration	Conical tubes with screw caps	Same
Kit configuration comes with a swab	Swab included	Same
Media volume	2mL	Same
General Device Characteristic Differences		
Microorganisms tested	<i>Escherichia coli</i> <i>Salmonella typhimurium</i> <i>Shigella sonnei</i> <i>Campylobacter jejuni</i> <i>Yersinia enterocolitica</i> <i>Vibrio parahaemolyticus</i> <i>Enterococcus faecalis</i> <i>Plesiomonas shigelloides</i> <i>Escherichia coli O157:H7</i> <i>Clostridium difficile</i>	<i>Escherichia coli</i> <i>Escherichia coli O157:H7</i> <i>Salmonella typhimurium</i> <i>Shigella sonnei</i> <i>Campylobacter jejuni</i> <i>Yersinia enterocolitica</i> <i>Vibrio parahaemolyticus</i> <i>Enterococcus faecalis</i> vancomycin resistant (VRE) <i>Clostridium difficile</i>
Medium formulation	Potassium di-hydrogen phosphate Di-sodium hydrogen phosphate Sodium thioglycollate Sodium chloride Calcium chloride Deionized water	Chloride salts Sodium salts Phosphate buffer L-Cysteine Agar Water
Shelf-life	24 months	15 months
Specific swab type	Foam tip	Flocked nylon tip

5. Intended Use

The Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device is intended to preserve the viability and infectivity of fecal specimens after their collection and during transport

from the collection site to the testing laboratory. The product can be used to collect stool specimen directly from the patient, using the swab as a rectal swab. Alternatively, the swab can be used to take material from a previously collected stool specimen. Fecal Transwab® specimens are processed using standard clinical laboratory operating procedures for microbiological specimens.

6. Technological Characteristics and Substantial Equivalence.

The Medical Wire Fecal Transwab® product is substantially equivalent to the previously cleared device. The previously cleared and the modified devices are swab transport systems using liquid transport medium. The previously cleared and the modified devices are identical in overall function. The modified device is intended only for the transport of fecal specimens.

7. Performance Testing

Shelf-life stability: The shelf-life stability was performed using a real-time study design with seven lots of media demonstrating stability for up to 24 months at room temperature.

Recovery studies: Roll-plate and swab elution studies were conducted to evaluate the performance characteristics of the Medical Wire Fecal Transwab® in accordance with CLSI “Quality Control of Microbiological Transport Systems”; Approved Standard M40-A2, but using recognised strains of fecal bacteria. The following list of organisms were tested:

- *Campylobacter jejuni* ATCC 33291
- *Enterococcus faecalis* ATCC 29212
- *Escherichia coli* ATCC 25922
- *Salmonella typhimurium* ATCC 14028
- *Shigella sonnei* (flexnuri) ATCC 12022
- *Vibrio parahaemolyticus* ATCC 17802
- *Yersinia enterocolitica* ATCC 9610
- *Plesiomonas shigelloides* ATCC 14029
- *Escherichia coli* 0157:H7 ATCC 700728
- *Clostridium difficile* ATCC 9689

Tests were performed to simulate transport at fridge temperature and room temperature. The tests included inoculation of suspensions prepared in a 50% fecal matrix to represent real life specimens. All organisms tested met the predefined acceptance criteria and demonstrated adequate recovery after storage at refrigeration (2-8°C) and room temperature (20-25°C) at 48 hrs except for *Clostridium difficile* that demonstrated adequate recovery up to 24hrs.

The data provided support a substantial equivalent decision.