December 16, 2022

Copan Italia S.p.A.
Elisabetta Zanella
Chief Regulatory Officer
via F. Perotti 10
Brescia, 25125
Italy

Re: K220052
Trade/Device Name: Copan FecalSwab Collection, Transport and Preservation System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: December 31, 2021
Received: January 6, 2022

Dear Elisabetta Zanella:

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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
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)*
K220052

Device Name
Copan FecalSwab Collection, Transport and Preservation System

Indications for Use *(Describe)*
The Copan FecalSwab Collection, Transport and Preservation System is intended for collection and preservation of viable enteric pathogenic bacteria from rectal swabs and stool specimens 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. Stool specimens collected with the Copan FecalSwab are also suitable for use with the BD MAX Enteric Bacterial Panel and the BD MAX Extended Enteric Bacterial Panel.

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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510K SUMMARY

Copan FecalSwab Collection, Transport and Preservation System Migration to BD MAX Enteric Bacterial Panel (EBP) & BD MAX Extended Bacterial Panel (xEBP)

1. General Information

Applicant/Sponsor: COPAN ITALIA
SpA Via F. Perotti
10 25125 Brescia, Italy
Tel. +39 030 2687212

Contact Person(s): Ms. Vanessa Bonomi
Ms. Elisabetta Zanella

Tel. +39 030 2687212
Email: regulatory.affairs@copangroup.com

Summary Prepared Date: 31st December 2021

2. Device

Trade Name:	Copan FecalSwab Collection, Transport and Preservation System
Common Name:	Collection and Transport Device
Classification Name:	Culture Media, Non-Propagating Transport
Classification Panel:	Microbiology
Classification Regulation:	21 CFR 866.2390
Product Code:	JSM, LIO
Class:	Class I

3. Predicate Device

Predicate device name (s):
Copan FecalSwab Collection, Transport and Preservation System – K142094

4. Device Description

The FecalSwab Collection, Transport and Preservation System (Copan FecalSwab) is supplied in a collection kit format. Each collection kit consists of a package containing a plastic tube filled with 2 mL of FecalSwab transport and preservation medium and a specimen collection flocked swab intended both for rectal and stool specimen collection. In the laboratory, rectal and stool specimen are processed using standard clinical laboratory operating procedures for culture.

The FecalSwab transport and preservation medium is a maintenance medium comprised of: Chloride salts, Sodium salts, Phosphate buffer, L-Cysteine and Agar. The medium is designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory

The Copan FecalSwab Collection, Transport and Preservation System was previously cleared (K142094) 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 specimen are intended be processed using standard clinical laboratory operating procedures for culture but is not cleared for use with downstream molecular assays. The FecalSwab has been demonstrated to be suitable for testing samples with the BD MAX Enteric Bacterial Panel (EBP) and BD MAX Extended Bacterial Panel (xEBP).

5. Indications for use

The Copan FecalSwab Collection, Transport and Preservation System is intended for collection and preservation of viable enteric pathogenic bacteria from rectal swabs and stool specimens 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. Stool specimens collected with the Copan FecalSwab are also suitable for use with the BD MAX Enteric Bacterial Panel and the BD MAX Extended Enteric Bacterial Panel.

Special conditions for use statement(s):
For prescription use only

Special Instrument Requirements:
The BD MAX Enteric Bacterial Panel and BD MAX Extended Enteric Bacterial Panel are for use on the BD MAX System.

6. Comparison with predicate

The Copan FecalSwab System is substantially equivalent to the predicate specimen collection and transport device. The Copan Fecal Swab System and the predicate device are similar in intended use and overall function.

Comparison table:

Device & Predicate Device(s):	**Device: K220052**	**Predicate: K142094**
Device Trade Name	Copan FecalSwab Collection, Transport and Preservation System	Copan FecalSwab Collection, Transport and Preservation System
General Device Characteristic	Copan FecalSwab is a Collection, Transport and Preservation System supplied in a collection kit format.	Copan FecalSwab is a Collection, Transport and Preservation System supplied in a collection kit format.
General Device Characteristic Similarities		
Intended Use; Collection Device	The Copan FecalSwab Collection, Transport and Preservation System is intended for collection and preservation of viable enteric pathogenic bacteria from rectal swabs and stool specimens during transport from the collection site to the testing laboratory for standard culture procedures. Stool specimens collected with the Copan FecalSwab are also suitable for use with the BD MAX Enteric Bacterial Panel and the BD MAX Extended Bacterial Panel.	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 **Note:** The scope of this clearance does not intend to seek claims for use of rectal specimens with the BD MAX EBP and xEBP Assays.	Same
Microorganisms supported	Enteric pathogenic bacteria	Same

Single Use Device	Yes	Same
Container	Polypropylene conical bottom vial	Same
Product Configuration	Medium in vial & cap System including Medium and swab in peel pouch option.	Same
pH of Medium	6.90 – 7.50	Same
Storage Temperature	5-25ºC	Same
Medium Volume	2 mL	Same
Swab Shaft	Plastic	Same
Swab Tip	Flocked nylon	Same
Shelf Life	15 months	Same
Medium Formulation	Chloride salts Sodium salts Phosphate buffer L-Cysteine Agar Distilled water	Same
Product code	JSM, LIO	Same
General Device Characteristic Differences		
Claimed instrument platforms	The BD MAX Enteric Bacterial Panel and the BD MAX Extended Enteric Bacterial Panel.	None
List of claimed organisms	*Escherichia coli* *Escherichia coli O157:H7* *Salmonella typhimurium* *Shigella sonnei* *Campylobacter jejuni* *Yersinia enterocolitica* *Vibrio parahaemolyticus* *Enterococcus faecalis* *Vancomycin resistant (VRE)* *Clostridium difficile* ***Plesiomonas shigelloides***	*Escherichia coli* *Escherichia coli O157:H7* *Salmonella typhimurium* *Shigella sonnei* *Campylobacter jejuni* *Yersinia enterocolitica* *Vibrio parahaemolyticus* *Enterococcus faecalis* *Vancomycin resistant (VRE)* *Clostridium difficile*

7. Summary of Performance Testing

Studies were conducted to evaluate the performance characteristics of the Copan FecalSwab System components as well as the complete FecalSwab collection kit formats.

Detection Limit

The LoD study using the Copan FecalSwab indicated that the FecalSwab Collection device did not influence the LoD of the BD MAX Enteric Bacterial Panel or BD MAX Extended Enteric Bacterial Panel.The pooled negative clinical stool matrix was pre-tested with an FDA cleared assay for each target organism and determined to be negative prior to use. The stool matrix was used as a negative sample or was spiked to generate positive samples with the following organisms: *Salmonella typhimurium*, ATCC 14028; *Escherichia coli* STX1, ATCC 43890; *Campylobacter jejuni*, ATCC 43429 and *Shigella sonnei*, ATCC 9290. A 0.5 McFarland standard was made for each organism and further diluted. The 0.5 McFarland was confirmed with culture to determine the CFU/mL concentration, each organism was then serially diluted down to the LoD. The LoD is reported in CFU/mL.

150 µL each of the inoculated stool samples was used to spike 12 tubes of the FecalSwab transport medium according to the IFU. After inoculation, 50 µL of each inoculated FecalSwab tube specimens were transferred into a total of 24 BD MAX sample buffer tubes (SBTs) in parallel according to the manufacturer's instructions for BD MAX assays. This procedure was repeated for each dilution and mix. The external controls were processed and tested as described in the BD MAX EBP and BD MAX xEBP IFUs. The LoD is the concentration at which > 95% of the sample tested positive. Table 1 and 2 include the LoD concentrations of organisms in CFU/mL when FecalSwab specimens were tested with the BD MAX EBP and BD MAX xEBP.

Table 1: Limit of Detection Concentrations (CFU/mL) for FecalSwab specimens tested with BD MAX Enteric Bacterial Panel

Specimen type	***Salmonella typhimurium*** **ATCC 14028**	***Escherichia coli STX1*** **ATCC 43890**	***Campylobacter jejuni*** **ATCC 43429**	***Shigella sonnei*** **ATCC 9290**
FecalSwab	7.16E+05	1.30E+05	1.17E+04	1.74E+05

Table 2: Limit of Detection Concentrations (CFU/mL) for FecalSwab specimens tested with BD MAX Extended Enteric Bacterial Panel

Specimen type	***Plesiomonas shigelloides*** **ATCC 14029**	***Yersinia enterocolitica*** **ATCC 9610**	***Vibrio parahaemolyticus*** **ATCC 17802**	***Escherichia coli ETEC*** **ATCC 35401**
FecalSwab	7.94E+04	1.23E+05	7.12E+04	1.23E+05

For each organism tested across both the BD MAX enteric bacterial panel and extended bacterial panel, an LoD was identified. These results support that the FecalSwab has equivalent analytical performance to raw stool when used with BD MAX EBP and BD MAX xEBP cleared devices.

Bacterial Recovery (Viability)

Bacterial Recovery (Viability) Studies in the original clearance for the Copan fecal swab (K142094) did not include *Plesiomonas shigelloides* (*P. shigelloides*) (ATCC 14029) as a claimed organism. *P. shigelloides* is a claimed organism on the BD MAX EBP and xEBP panel and as a result *P. shigelloides* is added to the claimed organisms for the subject

device. All other organisms claimed on the BD MAX EBP and xEBP panel have been previously validated with viability studies using the subject device (K142094). Recovery studies for P. *shigelloides* to evaluate viability using the FecalSwab to maintain viability were performed using the roll plate method and the swab elution method. The acceptance criteria for both methods were that, for cultures from transport medium tubes held at both 2 - 8ºC and 20 - 25ºC, they must remain within 2 $\log_{10}$ of the initial microorganism concentration (time point 0). All data demonstrated the ability of the FecalSwab to maintain viability of bacteria under the claimed conditions of use (table 3 and 4).

Table 3: Summary of *Plesiomonas shigelloides* Recovery Study (Swab Elution Method)

	Average CFU recovered from three lots					
Holding Temperature	**T=0**	**T=6h**	**T=24h**	**T=48h**	**T=72h**	**T=48/72 hrs. Log reduction (-) or Log increase (+)**
2-8°C	1.19E+03	1.17E+03	1.02E+03	9.26E+02	8.01E+02	-0.17
20-25°C	1.19E+03	1.09E+03	2.23E+03	4.95E+03	[redacted]	0.61

Table 4: Summary of *Plesiomonas shigelloides* Recovery Study (Roll Plate Method)

	Average CFU recovered from three lots					
Holding Temperature	**T=0**	**T=6h**	**T=24h**	**T=48h**	**T=72h**	**T=48/72 hrs. Log reduction (-) or Log increase (+)**
2-8°C	1.31E+02	1.11E+02	1.12E+02	1.17E+02	1.35E+02	0.01
20-25°C	1.31E+02	1.21E+02	1.83E+02	1.09E+03	[redacted]	0.92

Specimen Storage Stability

Nucleic acid storage and stability was evaluated for specimens stored in the FecalSwab collection device under the same storage conditions claimed in BD MAX EBP and BD MAX xEBP clearance when using preserved stool specimens. The original clearance for BD MAX EBP and BD MAX xEBP was 25 ± 2ºC for 24 hrs or 2-8ºC for 5 days prior to testing. A study was conducted to test the previously cleared stability claims of 25 ± 2ºC for 24 hrs or 2-8ºC for 5 days, using the subject transport device. Studies included a nested stability testing to show that specimens stored in FecalSwab medium at the described conditions (i.e., **Day 1**: 24 hours in FecalSwab at 25±2°C, **Day 3**: 24 hours in FecalSwab at 25±2°C + 48 hours at 25±2°C in SBT, **Day 6**: 24 hours in FecalSwab at 25±2°C+ 5 days at 2-8°C in SBT, **Day 5**: 5

days in FecalSwab at 2-8°C, **Day 7**: 5 days in FecalSwab at 2-8°C + 48 hours at 25±2°C in SBT, and **Day 10**: 5 days in FecalSwab at 2-8°C + 5 days at 2-8°C in SBT) continued to be stable at 2-8ºC for up to 120 hours (5 days) or at 25 ± 2ºC for up to 48 hours. The study included four panels consisting of two different organisms mixed into each panel. Each panel used clinical matrix and was contrived at a concentration of 2 x LoD (Table 5). The acceptance criteria for the Fecalswab were a minimum of 95% detection for all targets at 2-8ºC for up to 120 hours (5 days) or at 25 ± 2ºC for up to 48 hours when SBT was used as described above in parentheses and results showed that each organism tested for both BD MAX EBP and xEBP had ≥ 95% detection at all the target storage stability time points claimed in the package insert (as shown in Table 6).

Table 5: Specimen Stability Multiplex Organism Mix Compositions and Organisms Concentration in SBT during the test Expressed in Colony Forming Units (CFU/mL).

PANEL	ORGANISMS	CFUs/mL in SBT (LoD) from the PI	CFUs/mL in SBT (2XLoD) from the PI	Actual 2XLoD concentration of each strain in CFUs/mL SBT
BD MAX EBP multiplex mix #1	*Campylobacter jejuni*	10	20	56
	Shigella sonnei	124	248	144
BD MAX EBP multiplex mix #2	*Escherichia coli STX1*	223	446	361
	Salmonella typhimurium	193	386	373
BD MAX xEBP multiplex mix #1	*Yersinia enterocolitica*	227	454	576
	Escherichia coli ETEC	137	274	361
BD MAX xEBP multiplex mix #2	*Vibrio parahaemolyticus*	124	248	396
	Plesiomonas shigelloides	257	514	329

Table 6: Summary of FecalSwab specimen storage stability results with BD MAX EBP and BD MAX xEBP

	FecalSwab 25±2°C nested to SBT at 2-8°C and 25±2°C			FecalSwab 2-8°C nested to SBT at 2-8°C and 25±2°C		
Organism	**Day**	**N° positive replicates**	***% Pos***	**Day**	**N° positive replicates**	***% Pos***
***Plesiomonas shigelloides* ATCC 14029**	1	23/24	96	5	24/24	100
	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100
***Vibrio parahaemolyticus* ATCC 17802**	1	24/24	100	5	24/24	100
	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100
Yersinia enterocolitica	1	24/24	100	5	24/24	100

ATCC 9610	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100
Escherichia coli ETEC **ATCC 35401**	1	24/24	100	5	24/24	100
	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100
Campylobacter jejuni **ATCC 43429**	1	24/24	100	5	24/24	100
	3	24/24	100	7	24/24	100
	6	23/24	96	10	24/24	100
Shigella sonnei **ATCC 9290**	1	24/24	100	5	24/24	100
	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100
Escherichia coli STX1 **ATCC 43890**	1	24/24	100	5	24/24	100
	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100
Salmonella typhimurium **ATCC 14028**	1	24/24	100	5	24/24	100
	3	24/24	100	7	24/24	100
	6	24/24	100	10	24/24	100

PCR Interfering Substances

Exogenous interfering substance studies were conducted in the original BD MAX EBP and BD MAX xEBP clearance. An additional interference study was conducted to assess the contents of the Copan FecalSwab Collection, Transport and Preservation System using the sample processing control (SPC) that is included with BD MAX EBP and BD MAX xEBP assays. The SPC target is intended to monitor the presence of potential inhibitory substances in each reaction. In this case, the swabs were left inside the transport device tubes for the duration of the incubation period and amplification of the sample processing control (SPC) target was successful at every stability time point tested. The results indicate that there was no interference or inhibition in any of the component of the FecalSwab collection, transport, and preservation system. The SPC monitors DNA extraction, thermal cycling, reagent integrity and the presence of inhibitory substances. Results of tests are shown in table 7.

Table 7: PCR Interfering Substance SPC Results from FecalSwab Specimen Storage Stability Studies.

Specimen storage condition in FecalSwab	Specimen storage condition in SBT	Total Days	Number of replicates tested	Number of replicates providing amplification for SPC target
NA	NA	0	48	48/48
1 Day at 25±2°C	NA	1	24	24/24
2 Days at 25±2°C	NA	2	24	24/24

1 Day at 25±2°C	2 Days at 25±2°C	3	24	24/24
1 Day at 25±2°C	3 Days at 25±2°C	4	24	24/24
1 Day at 25±2°C	5 Days at 2-8°C	6	24	24/24
1 Day at 25±2°C	6 Days at 2-8°C	7	24	24/24
5 Days at 2-8°C	NA	5	24	24/24
6 Days at 2-8°C	NA	6	24	24/24
5 Days at 2-8°C	2 Days at 25±2°C	7	24	24/24
5 Days at 2-8°C	3 Days at 25±2°C	8	24	24/24
5 Days at 2-8°C	5 Days at 2-8°C	10	24	24/24
5 Days at 2-8°C	6 Days at 2-8°C	11	24	24/24

Microbial cross-reactivity

Microbial cross-reactivity studies were conducted in the original BD MAX EBP and BD MAX xEBP clearance. No modifications were made to the BD MAX EBP and BD MAX xEBP assay design, reagents, workflow, algorithm, or interpretation of results when the FecalSwab preserved stool specimens are used in combination with BD MAX EBP and BD MAX xEBP. Data indicates that the use of the FecalSwab to collect, transport and preserve stool specimens does not have any effect on the BD MAX EBP and BD MAX xEBP instruments or have any effect on signal overlap. As a result, not additional cross reactivity studies were conducted.

8. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was conducted to support this submission

9. Conclusions Drawn from Non-Clinical Tests

The similarities in the intended use, operational characteristics, and functional technological characteristics between the Copan FecalSwab system and the predicate led to a conclusion of substantial equivalence between the Copan FecalSwab and predicate device.