510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K162284

B. Purpose for Submission:

To make a substantial equivalence determination for the Puritan® Fecal Opti- Swab™ Collection and Transport System for the collection, transport and storage of fecal specimens for laboratory culture of bacteria and yeast.

C. Measurand:

Not applicable.

D. Type of Test:

Collection and transport culture medium device

E. Applicant:

Puritan Medical Products, LLC

F. Proprietary and Established Names:

Puritan® Fecal Opti- Swab™ Collection and Transport System

G. Regulatory Information:

1. Regulation section:

   866.2390; Transport Culture Medium

2. Classification:

   Class I

3. Product code:

   JSM: Culture Media, Non-Propagating Transport
   LIO: Device, Specimen Collection
   JTW: System, Transport, Aerobic

JTX: Trasport Systems, Anaerobic

4. Panel:

   83- Microbiology

H. Intended Use:

1. Intended use(s):

   Puritan Fecal Opti-Swab 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.

2. Indication(s) for use:

   Same as intended use.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   None.

I. Device Description:

Puritan Fecal Opti-Swab Collection and Transport System is comprised of a peel pouch containing a rayon tipped swab applicator for collecting specimens and a polypropylene, round-bottomed, capped tube containing 2 ml of a modified s Cary-Blair medium.

Cary-Blair medium is a non-nutritive 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 used to increase the viscosity of the medium. Sodium thioglycollate and L-cysteine helps maintain an oxygen-reduced environment to help maintain the viability of enteric bacteria during the transport to the laboratory.

The liquid modified Cary Blair medium is composed of the following components:

- Sodium chloride
- Disodium Phosphate
- Sodium thioglycollate
- Calcium chloride

- L-cysteine
- Bacteriological agar
- Deionized water

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Copan FecalSwab Collection, Transport and Preservation System

2. Predicate 510(k) number(s):

   K142094

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
	Puritan Fecal Opti-Swab Collection and Transport System (K162284)	**Copan FecalSwab Collection, Transport and Preservation System (K142094)**
Intended Use	Puritan Fecal Opti-Swab 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.	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 Storage	For *C. difficile*, up to 48 hours at 2 – 8 ^{o}C and up to 24 hours at 20 – 25 ^{o}C. For other target organisms organisms: up to 72 hours at 2 – 8 ^{o}C and up to 48 hours at 20 – 25 ^{o}C.	Same
Shelf life	15 months	Same
Medium Volume	2 mL	Same

Similarities		
Item	**Device**	**Predicate**
	Puritan Fecal Opti-Swab Collection and Transport System (K162284)	**Copan FecalSwab Collection, Transport and Preservation System (K142094)**
Single Use Device	Yes	Same
Tube	Polypropylene, conical with screw cap	Same
Packaging	Peel pouch	Same
Swab	Flocked rayon	Same
Organisms Tested	*Campylobacter jejuni* *Clostridium difficile* *Enterococcus faecalis* *Escherichia coli* *Salmonella typhimurium* *Shigella sonnei* *Vibrio parahaemolyticus* *Yersinia enterocolitica*	Same

Differences		
Item	**Device**	**Predicate**
	Puritan Fecal Opti-Swab Collection and Transport System (K162284)	**Copan FecalSwab Collection, Transport and Preservation System (K142094)**
Medium Formulation	Sodium chloride Disodium Phosphate Sodium thioglycollate L-cysteine Calcium chloride Bacteriological agar Deionized water	Chloride salts Sodium salts Phosphate buffer L-cysteine Agar Water
Medium	Liquid	Semi-solid

K. Standard/Guidance Document Referenced (if applicable):

Quality Control of Microbiological Transport Systems; Approved Standard – Second Edition, M40-A2, Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2014.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   The performance of the Puritan Fecal Opti-Swab Collection and Transport System was determined using roll plate and swab elution techniques outlined in the Clinical and Laboratory Standards Institute (CLSI) M40-A2 document. Bacterial viability studies were performed. The swabs from each transport system were inoculated with a specified volume of bacterial concentrations prepared in a fecal matrix and/or 0.85% phosphate buffered saline (PBS). A select group of organisms were also tested in a fecal matrix (See **Table 1**). Fecal matrix was made by diluting pre-screened negative fresh clinical fecal material in 0.85% PBS to a 30% concentration by volume.

   These swabs were then placed in their respective transport tubes and held at various time intervals; at the designated time intervals the swabs were removed and processed. To test the viability at various time intervals the inoculated swabs were held at room temperature for 0, 24, and 48 hours and refrigerated for 0, 24, 48, and 72 hours.

   The nine ATCC strains listed in **Table 1** below were used in this study to evaluate the performance of the Puritan Fecal Opti-Swab Collection and Transport System. This device was tested using the swabs included with the transport kit. Viability studies were conducted in duplicate at 0, 24, and 48 at room temperature (20-25°C) and at 0, 24, 48, and 72 hours at refrigerated temperatures (2-8°C) using the Roll-Plate and Swab Elution Methods for all strains except *C. difficile*. For *C. difficile*, viability studies were conducted in duplicate at 0 and 48 at room temperature (20-25°C) and at 0, 24 and 48 hours at refrigerated temperatures (2-8°C) using the Roll-Plate and Swab Elution Methods.

Table 1: Enteric bacteria evaluated for stability in Puritan Fecal Opti-Swab Collection and Transport System

Microorganism	ATCC #	Fecal Matrix*	0.85% Saline*
Campylobacter jejuni	ATCC 33291	NO	YES
Clostridium difficile	ATCC 9689	NO	YES
Enterococcus faecalis, Vancomycin-resistant (VRE)	ATCC 51299	NO	YES
Escherichia coli	ATCC 25922	NO	YES
Escherichia coli 0157:H7	ATCC 700728	YES	YES
Salmonella typhimurium	ATCC 14028	YES	YES
Shigella sonnei	ATCC 12022	NO	YES
Vibrio parahaemolyticus	ATCC 17802	YES	YES
Yersinia enterocolitica	ATCC 9610	NO	YES

* 'NO' indicates that strain was not tested in the column heading matrix;
'YES' indicates that the strain was tested in the column heading matrix.

Roll-Plate Method:
Bacterial suspensions were prepared from fresh18-24 hour cultures of each microorganism in a separate vial containing 10 mL of 0.85% sterile saline to obtain 1.5 x 10^8 CFU/mL suspensions. A select group of organisms were also tested in a separate vial

containing 10 mL fecal matrix. One log_{10} serial dilutions were made and 100 µL aliquots of dilutions were absorbed into the swabs and immediately placed into the Puritan Fecal Opti-Swab Collection and Transport System. For fecal specimens, the final dilution prior to swab inoculation was done with fecal matrix to maximize the amount of fecal material on the swab.

After incubation at each time point, the swabs were removed from the transport tubes and used to inoculate the entire surface of the appropriate agar plate. The plates were incubated in appropriate culture conditions for 24-48 hours or until countable colonies were visible. Manual colony counts were conducted for each time interval for each swab-organism combination. The dilution yielding colony counts within the countable tolerance zone (approximately between 25 and 250 colonies) was reported. Log_{10} increases or decreases in survival are based on a comparison between time-zero and the last time point collected for each temperature.

Swab Elution Method:
Bacterial suspensions were prepared from fresh18-24 hour cultures of each microorganism in a separate vial containing 10 mL of fecal matrix or 0.85% sterile saline to obtain 1.5 x 10^8 CFU/mL suspensions. The suspensions were diluted in 0.85% saline or fecal matrix solution to obtain working suspensions of 1.5 x 10^7 CFU/ml, and then 100 µL aliquots of dilutions were absorbed into the swabs and immediately placed into the Puritan Fecal Opti-Swab Collection and Transport System medium. After incubation at each time point, the swabs were removed from the transport tubes and 100 µL of 1-log_{10} serial dilutions were made in 0.85% saline. 100 µL of each dilution was plated on the appropriate agar plate for each temperature and time point. The plates were incubated in appropriate culture conditions for 24-48 hours or until countable colonies were visible. Manual colony counts were conducted for each time interval for each swab-organism combination. The dilution yielding zero-time colony counts approximately between 25 and 250 CFU was reported.

Results from the Roll Plate and Swab Elution experiments as determined at various storage times and temperature ranges are shown in **Tables 2-9** below.

Acceptance criteria for recovery of microorganisms is defined as being within one log_{10} increase or decrease from the starting titer at time zero. Manual colony counts were conducted for each of the time intervals for each microorganism held at each temperature.

Table 2. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from fecal matrix using Roll-Plate Method at 20-25°C					
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFUs Recovered: Time 0 h**	**Average CFUs Recovered: Time 24 h**	**Average CFUs Recovered: Time 48 h**
Escherichia coli 0157:H7 ATCC 700728	Diluted 10^{-4}	Puritan - 151002	51	145	269
		Puritan - 151026	38	118	244
		Puritan - 151105	44	126	257
Salmonella typhimurium ATCC 14028	Diluted 10^{-4}	Puritan - 151002	63	148	355
		Puritan - 151026	57	139	337
		Puritan - 151105	45	123	314
Vibrio parahaemolyticus ATCC 17802	Diluted 10^{-4}	Puritan - 151002	80	258	195
		Puritan - 151026	57	234	152
		Puritan - 151105	65	243	208

Table 3. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from fecal matrix using Roll-Plate Method at 2-8°C						
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFUs Recovered: Time 0 h**	**Average CFUs Recovered: Time 24 h**	**Average CFUs Recovered: Time 48 h**	**Average CFUs Recovered: Time 72 h**
Escherichia coli 0157:H7 ATCC 700728	Diluted 10^{-4}	Puritan - 151002	51	44	29	23
		Puritan - 151026	38	31	25	16
		Puritan - 151105	44	36	26	14
Salmonella typhimurium ATCC 14028	Diluted 10^{-4}	Puritan - 151002	63	49	37	21
		Puritan - 151026	57	51	42	33
		Puritan - 151105	45	36	29	22
Vibrio parahaemolyticus ATCC 17802	Diluted 10^{-4}	Puritan - 151002	80	125	69	53
		Puritan - 151026	57	93	46	39
		Puritan - 151105	65	109	61	47

Table 4. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from fecal matrix using Swab-Elution Method at 20-25°C						
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFU/ml Recovered: Time 0 h**	**Average CFU/ml Recovered: Time 24 h**	**Average CFU/ml Recovered: Time 48 h**	**Growth/ Death: Log_{10} (48h/0h)**
Escherichia coli 0157:H7 ATCC 700728	1:10	Puritan - 151002	4.7×10^5	1.21×10^6	2.48×10^6	0.72
		Puritan - 151026	3.2×10^5	1.06×10^6	$2.16x 10^6$	0.83
		Puritan - 151105	3.9×10^5	1.17×10^6	2.22×10^6	0.76
Salmonella typhimurium ATCC 14028	1:10	Puritan - 151002	2.9×10^5	8.4×10^6	1.51×10^6	0.72
		Puritan - 151026	7.1×10^5	$1.41x 10^6$	3.14×10^6	0.65
		Puritan - 151105	6.7×10^5	1.46×10^6	3.29×10^6	0.69
Vibrio parahaemolyticus ATCC 17802	1:10	Puritan - 151002	5.8×10^5	1.37×10^6	3.12×10^6	0.73
		Puritan - 151026	5.4×10^5	1.28×10^6	2.46×10^6	0.66
		Puritan - 151105	4.9×10^5	1.14×10^6	2.59×10^6	0.72

Table 5. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from fecal matrix using Swab-Elution Method at 2-8°C							
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFU/ml Recovered: Time 0 h**	**Average CFU/ml Recovered: Time 24 h**	**Average CFU/ml Recovered: Time 48 h**	**Average CFU/ml Recovered: Time 72 h**	**Growth/ Death: Log_{10} (72h/0h)**
Escherichia coli 0157:H7 ATCC 700728	1:10	Puritan - 151002	4.7×10^5	4.0×10^5	3.1×10^5	1.9×10^5	-0.39
		Puritan - 151026	3.2×10^5	2.7×10^5	2.0×10^5	1.5×10^5	-0.33
		Puritan - 151105	3.9×10^5	3.2×10^5	2.5×10^5	1.4×10^5	-0.44
Salmonella typhimurium ATCC 14028	1:10	Puritan - 151002	2.9×10^5	1.8×10^5	1.1×10^5	8.0×10^4	-0.56
		Puritan - 151026	7.1×10^5	6.3×10^5	4.8×10^5	3.6×10^5	-0.29
		Puritan - 151105	6.7×10^5	5.7×10^5	$4.1x 10^5$	2.9×10^5	-0.36
Vibrio parahaemolyticus ATCC 17802	1:10	Puritan - 151002	5.8×10^5	4.8×10^5	3.9×10^5	3.1×10^5	-0.27
		Puritan - 151026	5.4×10^5	4.5×10^5	3.2×10^5	2.4×10^5	-0.35
		Puritan - 151105	4.9×10^5	3.8×10^5	3.0×10^5	2.4×10^5	-0.31

Table 6. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from saline using Roll-Plate Method at 20-25°C					
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFUs Recovered: Time 0 h**	**Average CFUs Recovered: Time 24 h**	**Average CFUs Recovered: Time 48 h**
Campylobacter jejuni ATCC 33291	Diluted 10^{-4}	Puritan - 160311	238	165	31
		Puritan - 160315	246	172	27
		Puritan - 160322	231	158	23
Clostridium difficile ATCC 9689	Diluted 10^{-4}	Puritan - 160311	88	18	
		Puritan - 160315	62	13	
		Puritan - 160322	57	11	
Enterococcus faecalis, Vancomycin-resistant (VRE) ATCC 51299	Diluted 10^{-4}	Puritan - 160311	32	89	156
		Puritan - 160315	45	98	153
		Puritan - 160322	37	91	149
Escherichia coli ATCC 25922	Diluted 10^{-4}	Puritan - 160311	52	164	299
		Puritan - 160315	38	157	282
		Puritan - 160322	44	142	278
Escherichia coli 0157:H7 ATCC 700728	Diluted 10^{-4}	Puritan - 160311	56	137	254
		Puritan - 160315	43	123	209
		Puritan - 160322	34	116	196
Salmonella typhimurium ATCC 14028	Diluted 10^{-4}	Puritan - 160311	55	176	326
		Puritan - 160315	42	157	299
		Puritan - 160322	47	168	285
Shigella sonnei ATCC 12022	Diluted 10^{-4}	Puritan - 160311	40	153	275
		Puritan - 160315	56	269	314
		Puritan - 160322	30	146	251
Vibrio parahaemolyticus ATCC 17802	Diluted 10^{-4}	Puritan - 160311	80	236	328
		Puritan - 160315	73	224	316
		Puritan - 160322	67	215	311
Yersinia enterocolitica ATCC 9610	Diluted 10^{-4}	Puritan - 160311	58	216	315
		Puritan - 160315	65	228	356
		Puritan - 160322	51	209	318

Table 7. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from saline using Roll-Plate Method at 2-8°C						
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFUs Recovered: Time 0 h**	**Average CFUs Recovered: Time 24 h**	**Average CFUs Recovered: Time 48 h**	**Average CFUs Recovered: Time 72 h**
Campylobacter jejuni ATCC 33291	Diluted 10^{-4}	Puritan - 160311	238	196	167	149
		Puritan - 160315	246	202	180	163
		Puritan - 160322	231	187	172	145
Clostridium difficile ATCC 9689	Diluted 10^{-4}	Puritan - 160311	88	31	12	
		Puritan - 160315	62	26	9	
		Puritan - 160322	57	21	5	
Enterococcus faecalis, Vancomycin-resistant (VRE) ATCC 51299	Diluted 10^{-4}	Puritan - 160311	32	25	19	14
		Puritan - 160315	45	39	27	20
		Puritan - 160322	37	29	23	18
Escherichia coli ATCC 25922	Diluted 10^{-4}	Puritan - 160311	52	48	31	19
		Puritan - 160315	38	32	25	16
		Puritan - 160322	44	36	29	17
Escherichia coli 0157:H7 ATCC 700728	Diluted 10^{-4}	Puritan - 160311	56	47	34	26
		Puritan - 160315	43	38	31	23
		Puritan - 160322	34	29	24	19
Salmonella typhimurium ATCC 14028	Diluted 10^{-4}	Puritan - 160311	55	71	48	43
		Puritan - 160315	42	57	36	29
		Puritan - 160322	47	62	44	37
Shigella sonnei ATCC 12022	Diluted 10^{-4}	Puritan - 160311	40	34	28	22
		Puritan - 160315	56	47	42	33
		Puritan - 160322	30	23	19	14
Vibrio parahaemolyticus ATCC 17802	Diluted 10^{-4}	Puritan - 160311	80	92	65	42
		Puritan - 160315	73	85	57	45
		Puritan - 160322	67	78	49	38
Yersinia enterocolitica ATCC 9610	Diluted 10^{-4}	Puritan - 160311	58	74	50	43
		Puritan - 160315	65	86	53	47
		Puritan - 160322	51	68	38	31

Table 8. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from saline using Swab Elution Method at 20-25°C						
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFU/ml Recovered: Time 0 h**	**Average CFU/ml Recovered: Time 24 h**	**Average CFU/ml Recovered: Time 48 h**	**Growth/ Death: Log_{10} (48h/0h)**
Campylobacter jejuni ATCC 33291	1:10	Puritan - 160311	2.09×10^6	1.57×10^6	2.1×10^5	-1.00
		Puritan - 160315	2.24×10^6	1.64×10^6	2.4×10^5	-0.97
		Puritan - 160322	2.15×10^6	1.43×10^6	2.6×10^5	-0.92
Clostridium difficile ATCC 9689	1:10	Puritan - 160311	9.7×10^5	1.1×10^5		-0.95
		Puritan - 160315	7.4×10^5	6.0×10^4		-1.09
		Puritan - 160322	6.6×10^5	8.0×10^4		-0.92
Enterococcus faecalis, Vancomycin-resistant (VRE) ATCC 51299	1:10	Puritan - 160311	3.7×10^5	9.5×10^5	1.55×10^6	0.62
		Puritan - 160315	4.0×10^5	1.14×10^6	1.78×10^6	0.65
		Puritan - 160322	3.3×10^5	1.01×10^6	1.69×10^6	0.71
Escherichia coli ATCC 25922	1:10	Puritan - 160311	4.1×10^5	1.58×10^6	2.73×10^6	0.82
		Puritan - 160315	3.3×10^5	1.51×10^6	2.65×10^6	0.90
		Puritan - 160322	3.8×10^5	1.37×10^6	2.48×10^6	0.81
Escherichia coli 0157:H7 ATCC 700728	1:10	Puritan - 160311	4.6×10^5	1.53×10^6	2.39×10^6	0.72
		Puritan - 160315	3.8×10^5	1.45×10^6	1.95×10^6	0.71
		Puritan - 160322	3.4×10^5	1.30×10^6	2.18×10^6	0.81
Salmonella typhimurium ATCC 14028	1:10	Puritan - 160311	4.5×10^5	1.96×10^6	3.25×10^6	0.86
		Puritan - 160315	3.6×10^5	1.83×10^6	2.99×10^6	0.92
		Puritan - 160322	4.1×10^5	1.71×10^6	3.06×10^6	0.87
Shigella sonnei ATCC 12022	1:10	Puritan - 160311	3.4×10^5	1.42×10^6	2.56×10^6	0.88
		Puritan - 160315	4.2×10^5	1.57×10^6	2.79×10^6	0.82
		Puritan - 160322	2.9×10^5	1.39×10^6	2.38×10^6	0.91
Vibrio parahaemolyticus ATCC 17802	1:10	Puritan - 160311	5.7×10^5	2.61×10^6	3.57×10^6	0.80
		Puritan - 160315	4.8×10^5	2.53×10^6	3.72×10^6	0.89
		Puritan - 160322	3.6×10^5	2.28×10^6	3.02×10^6	0.92
Yersinia enterocolitica ATCC 9610	1:10	Puritan - 160311	4.9 x 105	2.21×10^6	3.27×10^6	0.82
		Puritan - 160315	5.0×10^5	2.39×10^6	3.56×10^6	0.85
		Puritan - 160322	3.5×10^5	2.16×10^6	3.02×10^6	0.94

Table 9. Recovery results for Puritan Fecal Opti-Swab Collection and Transport System from saline using Swab Elution Method at 2-8°C							
Microorganism	**0.5 McFarland microorganism suspension diluted with saline**	**Product Lot Numbers**	**Average CFU/ml Recovered: Time 0 h**	**Average CFU/ml Recovered: Time 24 h**	**Average CFU/ml Recovered: Time 48 h**	**Average CFU/ml Recovered: Time 72 h**	**Growth/ Death: Log_{10} (72h/0h)**
Campylobacter jejuni ATCC 33291	1:10	Puritan - 160311	2.09 x 106	1.76 x 10^6	1.52 x 10^6	1.37 x 10^6	-0.18
		Puritan - 160315	2.24 x 106	1.91 x 10^6	1.75 x 10^6	1.54 x 10^6	-0.16
		Puritan - 160322	2.15 x 106	1.83 x 10^6	1.67 x 10^6	1.45 x 10^6	-0.17
Clostridium difficile ATCC 9689	1:10	Puritan - 160311	9.7 x 10^5	2.8 x 10^5	1.0 x 10^5		-0.99
		Puritan - 160315	7.4 x 10^5	2.3 x 10^5	7.0 x 10^4		-1.02
		Puritan - 160322	6.6 x 10^5	1.7 x 10^5	5.0 x 10^4		- 1.12
Enterococcus faecalis, Vancomycin-resistant (VRE) ATCC 51299	1:10	Puritan - 160311	3.7 x 10^5	3.0 x 10^5	2.2 x 10^5	1.4 x 10^5	-0.42
		Puritan - 160315	4.0 x 10^5	2.9 x 10^5	2.0 x 10^5	1.2 x 10^5	-0.52
		Puritan - 160322	3.3 x 10^5	2.7 x 10^5	1.9 x 10^5	1.1 x 10^5	-0.48
Escherichia coli ATCC 25922	1:10	Puritan - 160311	4.1 x 10^5	3.4 x 10^5	1.6 x 10^5	1.1 x 10^5	-0.57
		Puritan - 160315	3.3 x 10^5	2.5 x 10^5	1.8 x 10^5	1.3 x 10^5	-0.40
		Puritan - 160322	3.8 x 10^5	3.1 x 10^5	2.1 x 10^5	1.7 x 10^5	-0.35
Escherichia coli 0157:H7 ATCC 700728	1:10	Puritan - 160311	4.6 x 10^5	3.9 x 10^5	2.7 x 10^5	1.9 x 10^5	-0.38
		Puritan - 160315	3.8 x 10^5	3.1 x 10^5	2.4 x 10^5	1.7 x 10^5	-0.35
		Puritan - 160322	3.4 x 10^5	2.6 x 10^5	1.9 x 10^5	1.2 x 10^5	-0.45
Salmonella typhimurium ATCC 14028	1:10	Puritan - 160311	4.5 x 10^5	3.8 x 10^5	2.6 x 10^5	1.8 x 10^5	-0.40
		Puritan - 160315	3.6 x 10^5	3.2 x 10^5	2.3 x 10^5	1.6 x 10^5	-0.35
		Puritan - 160322	4.1 x 10^5	3.4 x 10^5	2.8 x 10^5	2.0 x 10^5	-0.31
Shigella sonnei ATCC 12022	1:10	Puritan - 160311	3.4 x 10^5	2.6 x 10^5	1.8 x 10^5	1.2 x 10^5	-0.45
		Puritan - 160315	4.2 x 10^5	3.7 x 10^5	2.9 x 10^5	2.1 x 10^5	-0.30
		Puritan - 160322	2.9 x 10^5	2.3 x 10^5	1.7 x 10^5	1.0 x 10^5	-0.46
Vibrio parahaemolyticus ATCC 17802	1:10	Puritan - 160311	5.7 x 10^5	7.2 x 10^5	4.5 x 10^5	3.8 x 10^5	-0.18
		Puritan - 160315	4.8 x 10^5	6.6 x 10^5	4.1 x 10^5	3.3 x 10^5	-0.16
		Puritan - 160322	3.6 x 10^5	5.2 x 10^5	3.2 x 10^5	2.7 x 10^5	-0.12
Yersinia enterocolitica ATCC 9610	1:10	Puritan - 160311	4.9 x 10^5	6.4 x 10^5	3.8 x 10^5	2.5 x 10^5	-0.29
		Puritan - 160315	5.0 x 10^5	6.7 x 10^5	4.3 x 10^5	3.3 x 10^5	-0.18
		Puritan - 160322	3.5 x 10^5	5.2 x 10^5	3.1 x 10^5	2.0 x 10^5	-0.24

These results demonstrate that the pre-defined acceptance criteria were met for each bacterial strain tested by both the Roll-Plate and Swab Elution Methods. Those results are described in labeling.

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Shelf-life Stability: Shelf life stability test were performed successfully on three lots of product demonstrating stability for up to 15 months at room temperature. Recovery of microorganisms from fecal matrix was assessed by the Roll Plate method, as described in M.1 above.

pH Stability: The pH of the test device was measured at predetermined time intervals up to 20 months after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan Fecal Opti-Swab Collection and Transport System. All samples tested were found to maintain pH within the specified range of pH 6.90 to 7.50.

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

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

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.