510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k131630

B. Purpose for Submission:

To make a substantial equivalence determination for the Puritan® Amies Medium Collection and Transport System for the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

C. Measurand:

Not applicable.

D. Type of Test:

Transport culture medium device

E. Applicant:

Puritan® Medical Products LLC

F. Proprietary and Established Names:

Puritan® Amies Medium Collection and Transport System

G. Regulatory Information:

1. Regulation section:

866.2900; Microbiological specimen collection and transport devices

2. Classification:

Class I

3. Product code:

LIO: Device, Specimen Collection
JTW: System, Transport, Aerobic
JTX: Transport Systems, Anaerobic

4. Panel:

83- Microbiology

H. Intended Use:

1. Intended use(s):

   Puritan® Amies Medium Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

2. Indication(s) for use:

   Same as intended use(s).

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   None.

I. Device Description:

Puritan® Amies Medium Collection and Transport System is comprised of a sterile peel pouch containing a rayon tipped swab applicator for collecting specimen and a polypropylene tube containing 4 ml of Amies medium with or without charcoal. The rayon tipped swab applicators are provided in different tip sizes to accommodate various specimen types.

Amies medium is a non-nutritive balanced salt solution containing inorganic phosphates to provide buffering capability, sodium chloride, potassium chloride, calcium chloride and magnesium chloride to provide essential ions that help maintain osmotic balance. Agar is a solidifying agent and gives a semi-solid texture to the medium. Sodium thioglycolate provides a reduced environment. It is recommended for maintaining the viability of aerobic, anaerobic and fastidious bacteria such as *Neisseria gonorrhoeae* during the transport to the laboratory. It also contains thioglycolate salt to provide a reduced environment and chloride salts to help maintain osmotic balance and control permeability of bacterial cells.

Approximate Amies medium without charcoal formulation per liter:

Sodium chloride	3.0g
Disodium phosphate	1.2g
Sodium thioglycolate	1.0g
Monopotassium phosphate	0.2g
Potassium chloride	0.2g
Calcium chloride	0.1g
Magnesium chloride	0.1g
Bacteriological agar	6.5g

The Puritan® Amies Medium Collection and Transport System with charcoal has the same formulation as above with the addition of 10g of charcoal.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Copan Venturi Transystem Amies Medium Without Charcoal

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

   k972448

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
	Puritan® Amies Medium Collection and Transport System (131630)	**Copan Venturi Transystem Amies Medium Without Charcoal (k972448)**
Intended Use	Puritan® Amies Medium Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.	The Copan Venturi Transystem Amies Medium Without Charcoal products are sterile, single-use specimen collection chambers intended to preserve the viability of microorganisms after their collection and during their transport from the collecting area to the laboratory. These devices are intended for the collection, transport, and preservation of clinical specimens for bacteriological examination. Copan Venturi Transystem Amies Medium Without Charcoal is designed to support the viability of a wide variety of clinically important aerobic and anaerobic bacteria.
Indication for Use	Same as intended use.	Same as intended use.
Single-Use Device	Yes	Same
Medium Formulation	Sodium chloride Disodium phosphate Sodium thioglycollate Monopotassium phosphate Potassium chloride Calcium chloride Magnesium chloride Bacteriological agar (Amies with charcoal has the same formulation as above with the addition of charcoal.)	Same
pH	7.3 ± 0.2	Same
Storage Temperature	4-25°C (refrigerated and room temperature)	Same

Container	Plastic round bottom tube	Same
Product Configuration	Medium in tubes & Plug System including Medium and swab in peel pouch option.	Same
Swab Shaft	Plastic	Same
Swab Tip	Rayon tipped swab	Same
Shelf Life	24 months	Same

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

Quality Control of Microbiological Transport Systems; Approved Standard, M40-A, Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2003.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The performance characteristics of Puritan® Amies Medium with and without charcoal were determined using the Roll Plate Method outlined in the Clinical and Laboratory Standards Institute (CLSI) M40-A document using different rayon-tipped swab types designed for throat, urogenital and nasal specimen collection. A variety of aerobic, anaerobic, and fastidious organisms were included in this study. The test organisms comprised of the ten ATCC strains that are recommended in the CLSI M40-A document for determining performance characteristics of swab transport systems. To determine the performance characteristics of the Puritan® Amies Medium with and without charcoal, bacterial viability studies were performed. These studies were conducted in refrigerated (4-8^{o}C) and room temperature (20-25°C) conditions. The swabs from each transport system were inoculated in duplicate with a specified volume of select bacterial concentrations. These swabs were then placed in their respective transport vial and held for 0, 24, and 48 hours; at the designated time intervals the swabs were removed and processed.

Organisms evaluated:

A. Aerobes and Facultative Anaerobes:

1. *Pseudomonas aeruginosa* ATCC BAA-427
2. *Streptococcus pyogenes* ATCC 19615
3. *Streptococcus pneumoniae* ATCC 6305
4. *Haemophilus influenzae* ATCC 10211

B. Anaerobes

1. *Bacteroides fragilis* ATCC 25285
2. *Peptostreptococcus anaerobius* ATCC 27337
3. *Fusobacterium nucleatum* ATCC 25586
4. *Propionibacterium acnes* ATCC 6919
5. *Prevotella melaninogenica* ATCC 2584

C. Fastidious

1. *Neisseria gonorrhoeae* ATCC 43069

Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A are followed. Manual colony counts were conducted for the Roll-Plate Method at all three time intervals for each swab-organism combination and the average was recorded. Three dilutions were analyzed for each test organism and the dilution yielding zero-time colony counts nearest to 300 CFU was reported. These viability results are acceptable.

The results of the study by Roll-Plate Method are presented in Tables 1-4 below for 3 lots of media each for the media formulations with and without charcoal. The results demonstrate that the Puritan® Amies Medium with and without charcoal were able to maintain the viability of all organisms up to 48 hours at room temperature (20-25^{o}C) and under refrigerated (4-8^{o}C) conditions. *Neisseria gonorrhoeae* results support acceptable recoveries up to 24 h, as recommended in the CLSI guidance M40-A. There is no CLSI M40-A interpretation for *N. gonorrhoeae* beyond 24 h of storage using the Roll Plate Method.

Viability performance studies on all of the organisms above also included an assessment of performance evaluation and overgrowth per CLSI M40-A section 7.12.1 – 7.12.5. Overgrowth assessment as defined in CLSI M40-A guideline is greater than one-$\log_{10}$ increase in CFU between zero-time and the holding time point. There was no increase in bacterial count for all organisms tested when the samples were stored at room temperature. The data provided is in conformance with the guidelines in CLSI M40-A at room temperature.

Table 1. Bacterial recovery results for Puritan Amies Medium without Charcoal using the Roll-Plate Method at room temperature conditions.

Organism	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
Pseudomonas aeruginosa ATCC BAA-427	Diluted 10^{-5}	Puritan - 121026	148	64	38
		Puritan - 121102	161	83	49
		Puritan - 121217	130	49	25
Streptococcus pyogenes ATCC 19615	Diluted 10^{-4}	Puritan - 121026	280	263	220
		Puritan - 121102	291	286	206
		Puritan - 121217	240	210	200
Streptococcus pneumoniae ATCC 6305	Diluted 10^{-4}	Puritan - 121026	207	74	46
		Puritan - 121102	126	63	13
		Puritan - 121217	200	150	62
Haemophilus influenzae ATCC 10211	Diluted 10^{-4}	Puritan - 121026	152	108	82
		Puritan - 121102	206	105	50
		Puritan - 121217	181	80	54
Bacteroides fragilis ATCC 25285	Diluted 10^{-5}	Puritan - 121026	285	110	109
		Puritan - 121102	260	188	166
		Puritan - 121217	260	130	130
Peptostreptococcus anaerobius ATCC 27337	Diluted 10^{-5}	Puritan - 121026	92	40	24
		Puritan - 121102	86	60	42
		Puritan - 121217	95	71	59
Fusobacterium nucleatum ATCC 25586	Diluted 10^{-4}	Puritan - 121026	159	76	31
		Puritan - 121102	150	60	45
		Puritan - 121217	145	110	106
Propionibacterium acnes ATCC 6919	Diluted 10^{-4}	Puritan - 121026	116	95	61
		Puritan - 121102	123	82	53
		Puritan - 121217	110	70	37
Prevotella melaninogenica ATCC 25845	Diluted 10^{-4}	Puritan - 121026	112	44	29
		Puritan - 121102	131	89	38
		Puritan - 121217	115	62	26
Neisseria gonorrhoeae ATCC 43069	Diluted 10^{-5}	Puritan - 121026	160	60	
		Puritan - 121102	216	69	
		Puritan - 121217	132	101	

Table 2. Bacterial recovery results for Puritan Amies Medium with Charcoal using the Roll-Plate Method at room temperature conditions.

Organism	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
Pseudomonas aeruginosa ATCC BAA-427	Diluted 10^{-4}	Puritan - 121203	124	44	27
		Puritan - 121217	110	26	14
		Puritan - 130111	132	112	76
Streptococcus pyogenes ATCC 19615	Diluted 10^{-4}	Puritan - 121203	248	167	126
		Puritan - 121217	290	276	250
		Puritan - 130111	270	123	90
Streptococcus pneumoniae ATCC 6305	Diluted 10^{-4}	Puritan - 121203	224	100	21
		Puritan - 121217	111	76	40
		Puritan - 130111	128	52	42
Haemophilus influenzae ATCC 10211	Diluted 10^{-4}	Puritan - 121203	144	74	24
		Puritan - 121217	277	178	75
		Puritan - 130111	215	88	60
Bacteroides fragilis ATCC 25285	Diluted 10^{-5}	Puritan - 121203	198	123	86
		Puritan - 121217	138	125	38
		Puritan - 130111	195	135	64
Peptostreptococcus anaerobius ATCC 27337	Diluted 10^{-5}	Puritan - 121203	235	100	82
		Puritan - 121217	206	41	20
		Puritan - 130111	190	28	21
Fusobacterium nucleatum ATCC 25586	Diluted 10^{-4}	Puritan - 121203	240	159	90
		Puritan - 121217	295	162	36
		Puritan - 130111	245	214	46
Propionibacterium acnes ATCC 6919	Diluted 10^{-4}	Puritan - 121203	70	50	45
		Puritan - 121217	70	27	21
		Puritan - 130111	80	23	18
Prevotella melaninogenica ATCC 25845	Diluted 10^{-4}	Puritan - 121203	144	88	39
		Puritan - 121217	170	111	68
		Puritan - 130111	129	94	55
Neisseria gonorrhoeae ATCC 43069	Diluted 10^{-5}	Puritan - 121203	82	64	
		Puritan - 121217	107	73	
		Puritan - 130111	67	26	

Table 3. Bacterial recovery results for Puritan Amies Medium without Charcoal using the Roll-Plate Method at refrigerated (4-8°C) conditions.

Organism	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
Pseudomonas aeruginosa ATCC BAA-427	Diluted 10^{-5}	Puritan - 121026	230	178	131
		Puritan - 121102	286	219	195
		Puritan - 121217	185	122	89
Streptococcus pyogenes ATCC 19615	Diluted 10^{-4}	Puritan - 121026	233	210	206
		Puritan - 121102	267	235	229
		Puritan - 121217	251	234	219
Streptococcus pneumoniae ATCC 6305	Diluted 10^{-4}	Puritan - 121026	239	153	113
		Puritan - 121102	218	169	138
		Puritan - 121217	189	151	129
Haemophilus influenzae ATCC 10211	Diluted 10^{-4}	Puritan - 121026	176	130	115
		Puritan - 121102	194	146	121
		Puritan - 121217	169	132	104
Bacteroides fragilis ATCC 25285	Diluted 10^{-5}	Puritan - 121026	265	224	179
		Puritan - 121102	274	246	211
		Puritan - 121217	211	192	157
Peptostreptococcus anaerobius ATCC 27337	Diluted 10^{-5}	Puritan - 121026	113	78	61
		Puritan - 121102	80	63	55
		Puritan - 121217	91	75	66
Fusobacterium nucleatum ATCC 25586	Diluted 10^{-4}	Puritan - 121026	184	159	120
		Puritan - 121102	153	118	94
		Puritan - 121217	169	130	119
Propionibacterium acnes ATCC 6919	Diluted 10^{-4}	Puritan - 121026	135	128	115
		Puritan - 121102	112	87	65
		Puritan - 121217	129	113	91
Prevotella melaninogenica ATCC 25845	Diluted 10^{-4}	Puritan - 121026	144	91	57
		Puritan - 121102	157	132	88
		Puritan - 121217	125	84	68
Neisseria gonorrhoeae ATCC 43069	Diluted 10^{-5}	Puritan - 121026	168	99	
		Puritan - 121102	179	112	
		Puritan - 121217	174	128	

Table 4. Bacterial recovery results for Puritan Amies Medium with Charcoal using the Roll-Plate Method at refrigerated (4-8°C) conditions.

Organism	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
Pseudomonas aeruginosa ATCC BAA-427	Diluted 10^{-5}	Puritan - 121203	140	131	110
		Puritan - 121217	133	117	86
		Puritan - 130111	158	120	109
Streptococcus pyogenes ATCC 19615	Diluted 10^{-4}	Puritan - 121203	225	196	165
		Puritan - 121217	238	204	185
		Puritan - 130111	244	212	189
Streptococcus pneumoniae ATCC 6305	Diluted 10^{-4}	Puritan - 121203	255	143	91
		Puritan - 121217	216	168	139
		Puritan - 130111	228	179	158
Haemophilus influenzae ATCC 10211	Diluted 10^{-4}	Puritan - 121203	249	216	178
		Puritan - 121217	167	125	88
		Puritan - 130111	209	162	122
Bacteroides fragilis ATCC 25285	Diluted 10^{-5}	Puritan - 121203	174	142	118
		Puritan - 121217	151	116	94
		Puritan - 130111	183	161	133
Peptostreptococcus anaerobius ATCC 27337	Diluted 10^{-5}	Puritan - 121203	246	141	100
		Puritan - 121217	198	129	64
		Puritan - 130111	224	118	76
Fusobacterium nucleatum ATCC 25586	Diluted 10^{-4}	Puritan - 121203	213	131	82
		Puritan - 121217	281	174	115
		Puritan - 130111	276	162	126
Propionibacterium acnes ATCC 6919	Diluted 10^{-4}	Puritan - 121203	113	94	87
		Puritan - 121217	95	85	61
		Puritan - 130111	86	71	47
Prevotella melaninogenica ATCC 25845	Diluted 10^{-4}	Puritan - 121203	159	114	86
		Puritan - 121217	189	138	112
		Puritan - 130111	134	103	72
Neisseria gonorrhoeae ATCC 43069	Diluted 10^{-5}	Puritan - 121203	126	111	
		Puritan - 121217	115	89	
		Puritan - 130111	139	123	

a. *Precision/Reproducibility:*

Not applicable.

b. *Linearity/assay reportable range:*

Not applicable.

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

Accelerated shelf life stability test were performed successfully on 3 lots of product demonstrating stability for up to 24 months at room temperature.

pH Stability: The pH of the test device was measured at predetermined time intervals up to 24 month after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan Amies Medium. All samples tested were found to maintain pH within the specified range.

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 Amies Medium 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. <u>Comparison studies:</u>

a. *Method comparison with predicate device:*

Method comparison is not applicable for a bacterial transport medium. The device itself does not provide a result that can be used in making a clinical decision.

Bench testing studies were done to determine the ability of the Puritan® Amies Medium Collection and Transport System to maintain viability of different strains of aerobes, anaerobes and fastidious bacteria. It showed recovery of bacteria within the acceptance criteria recommended in the CLSI M40-A guidelines like the predicate device. (See above under Performance Characteristics).

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