510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K220739

B Applicant

Zhejiang Gongdong Medical Technology Co., Ltd.

C Proprietary and Established Names

Disposable Urine Collection Tube

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JSM	Class I, reserved	21 CFR 866.2390 - Transport Culture Medium	MI - Microbiology
LIO	Class I, reserved	21 CFR 866.2900 - Microbiological specimen collection and transport device	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Disposable Urine Collection Tubes for the collection, transport, and preservation of urine specimen from the collection site to the testing laboratory for the cultivation of uropathogenic bacteria and yeasts.

B Measurand:

Not applicable

C Type of Test:

Non-propagating Transport Device

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
Disposable Urine Collection Tube is intended for the collection, transport and preservation of urine specimens from the collection site to the testing laboratory. In the laboratory, urine specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:
The Disposable Urine Collection Tubes for the collection, transport and preservation system consist of a safety rubber plug, a plastic cap and boric acid as an additive inside the tube. The tube is made of Polyethylene terephthalate (PET) and the safety plug is made of butyl-rubber while the disposable cap is made of Polyethylene (PE). The disposable tube device sustains the viability of organisms during transport for up to 48 hrs. at 2-4ºC and 22-25ºC.There are two main tube types (round and conical bottom), and four configurations by volume of urine for the round bottom tubes (4 ml, 7 ml, 8 ml, 10 ml). The conical bottom tubes only have one configuration by volume (8 ml). Each volume is available in yellow and white caps. The different device configurations and information on the amount of preservative contained in each tube is provided in table 1.

Table 1. Disposable Tubes Description and Packaging configurations

Ref No.	Draw volume (mL)	Tube size (Diameter × Length) in mm	Additive Boric acid in mg	Material	Type of tube	Cap color
GD040UB	4	13×75	40	PET	Round bottom	yellow
GD040UBW	4	13×75	40	PET	Round bottom	white
GD070UB	7	13×100	70	PET	Round bottom	yellow
GD070UBW	7	13×100	70	PET	Round bottom	white
GD080UB	8	16×100	80	PET	Round bottom	yellow

GD080UBW	8	16×100	80	PET	Round bottom	white
GD100UB	10	16×100	100	PET	Round bottom	yellow
GD100UBW	10	16×100	100	PET	Round bottom	white
GD080UAC	8	16×100	80	PET	Conical bottom	yellow
GD080UACW	8	16×100	80	PET	Conical bottom	white

B Principle of Operation:

The Disposable Urine Collection Tube system is used to safely collect and transport urine from collection sites to the testing laboratories. It is intended to be used by health care professionals. The vacuum in the collection tube allows autofill the urine sample through the puncture needle and the boric acid in the tubes prevents overgrowth of uropathogenic bacteria and yeasts.

V Substantial Equivalence Information:

A Predicate Device Name(s):
UriSwab-Urine Collection, Transport and Preservation System

B Predicate 510(k) Number(s):
K180052

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K220739	Predicate: K180052
Device Trade Name	Disposable Urine Collection Tube	UriSwab-Urine Collection, Transport and Preservation System
Device Product Code and Classification	JSM, LIO, Class I	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Disposable Urine Collection Tube is intended for the collection, transport, and preservation of urine specimens from the collection site to the testing laboratory. In the laboratory, urine	Copan UriSwab - Urine Collection, Transport and Preservation System is intended for the collection, transport, and preservation of urine specimens from the collection site to the testing laboratory. In

	specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.	the laboratory, UriSwab specimens are processed using standard clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.
Specimen Stability	2-4°C and 22-25°C; 48 hrs.	Same
Device Storage Temperature	22-25°C	Same
Sterilization	Radiation	Same
Sterile	Yes; 10^{-6} SAL	Same
General Device Characteristic Differences		
Tube material	Polyethylene Terephthalate (PET)	Plastic
Tube type	Round and Conical bottom	Conical bottom
Tube size	13 mm × 75 mm; 13 mm × 100 mm; 16 mm × 100 mm	12 mm × 80 mm; 16 mm × 100 mm
Tube volume	4 ml, 7 ml, 8 ml, 10 ml	1.5 ml, 3.2 ml
Cap	Safety cap, yellow and white.	Screw cap, yellow
Additive	Boric acid	Boric acid and Sodium formate
Collection device	PET tube with additive	Plastic tube, stick with sponge
Tube filling	Predefined vacuum	Sponge applicator

VI Standards/Guidance Documents Referenced:

Quality Control of Microbiological Transport Systems, Clinical and Laboratory Standards Institute (CLSI) guideline M40-A2, 2015.

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices, 1st edition, 11137-1, International Organization for Standardization (ISO), 2006.

Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, 3rd edition, 11137-2, International Organization for Standardization (ISO), 2013.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not Applicable

2. Linearity:

   Not Applicable

3. Analytical Specificity/Interference:

   Not Applicable

4. Assay Reportable Range:

   Not Applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Stability Verification Report:
   The shelf life for the Disposable Urine Collection Tube was determined to be 18 months from the date of manufacture when stored in well-ventilated clean room with the environment of relative humidity not more than 80% and at temperature 22 – 25ºC. The shelf life of the Disposable Urine Collection Tube was evaluated using real-time aging performance test at time points T = 0, 6, 12 and 18 months. At each time point, the following performance tests were conducted as described below:

   - Appearance test was carried out by inspecting visually for clear label, transparent PET tube and any sign of deformation or breakage.
   - Vacuum test was performed by measuring volume drawn into the Disposable Urine Collection Tube between 90 to 110% of the nominal liquid capacity allowed.
   - Physical and mechanical performance tests included leak test, strength test, and a 50 KPa pressure test.
   - Mechanical stress test was conducted by checking the tubes could withstand centrifugation.
   - The strength test, and urine collection volume capacity test were carried out as part of the evaluation.
   - Sterility test and the standard of boric acid content used were also assessed.
   - The package integrity was evaluated by visually checking for any changes or damage to the package. Six lots of varying production were used for the studies and results showed that all samples passed the real time aging test for 18 months at 22-25ºC.

   All the results were acceptable and support the claim that the Disposable Urine Collection Tube is physically or visually stable for 18 months.

Sterilization:

The Disposable Urine Collection Tubes were sterilized by electron beam radiation with an average dose of 20 kGy to achieve a sterility assurance level (SAL) of 10^{-6} with a dosimeter attached to monitor dosage through the sterilization process. Sterilization was validated following ISO 11137-1: 2006 and ISO 11137-2: 2013 Sterilization of Health Care Products Radiation guidelines. Sterility test was carried out according to ISO11137-2:2009 Medical Devices Radiation Sterilization-Microbiological Methods-Part 2. In this sterility test, 100 samples after irradiated at the verification dose were inoculated with 200 ml soybean casein liquid medium and incubated at 30±2°C for 14 days. The results were observed with no growth. Sterilization studies of the tube were acceptable.

6. Detection Limit:

Microbial Recovery Studies:

Microbial recovery (viability) studies were conducted to support the claim of the Disposable Urine Collection Tube for the collection, transport and preservation of urine specimens from the collection site to the testing laboratory. Sample panels were prepared from the listed bacteria and yeast (below) that were commonly associated with urinary tract infections. Cultures from 1.5×10^8 (equivalent 0.5 McFarland standard) were diluted into the pooled human negative clinical urine matrix to give a final concentration of 1.5×10^2 CFU/ml. The appropriate volume of urine samples spiked with each organism was introduced into the Disposable Urine Collection Tubes. Three lots of the Disposable Urine Collection Tubes with three samples per lot were evaluated for the microbial recovery (viability) assay. The inoculated sample tubes were initially tested to establish a time point zero then stored at 2-4ºC and 22-25ºC for 24 hrs., and 48 hrs. After each storage time and temperature, the samples were plated to grow colonies which were counted to determine CFU/ml for each time points. According to CLSI document M40-A2, the acceptance criteria for microbial recovery method was set to be within 1 $\log_{10}$ of the initial microorganism count. Results of recovery studies are presented in table 2.

Table 2. Performance of Disposable Urine Collection Tube in Microbial Recovery Studies

Strain tested	Storage temperature	Average CFU/ml recovered (N=9) at time points			Change in Log_{10} (0 - 48 hrs)
		0 hr	24 hrs	48 hrs	
Candida albicans (ATCC 24433)	2-4°C	140	107	85	-0.22
	22-25°C	140	74	69	-0.31
Escherichia coli (ATCC 25922)	2-4°C	137	104	92	-0.17
	22-25°C	137	85	42	-0.51
Enterococcus faecalis (ATCC 29212)	2-4°C	145	102	91	-0.20
	22-25°C	145	80	54	-0.43
Pseudomonas aeruginosa (ATCC 27853	2-4°C	143	103	69	-0.32
	22-25°C	143	106	72	-0.30
Proteus mirabilis (ATCC 7002)	2-4°C	140	111	72	-0.29
	22-25°C	140	105	71	-0.29
Staphylococcus saprophyticus	2-4°C	139	109	69	-0.30

(ATCC 15305)	22-25°C	139	108	66	-0.32
Citrobacter freundii (ATCC 8090)	2-4°C	140	104	73	-0.28
	22-25°C	140	105	73	-0.28
Candida glabrata (ATCC MYA-2950)	2-4°C	137	111	77	-0.25
	22-25°C	137	102	77	-0.25
Enterobacter cloacae (ATCC 13047)	2-4°C	138	107	67	-0.31
	22-25°C	138	81	69	-0.30
Morganella morganii (ATCC 25829)	2-4°C	139	111	69	-0.30
	22-25°C	139	110	53	-0.42
Streptococcus agalactiae (ATCC 12386)	2-4°C	143	112	69	-0.32
	22-25°C	143	112	71	-0.30

The microbial recovery studies demonstrated acceptable results.

Fill Volume Impact Recovery Study:

A fill volume impact recovery study was performed to demonstrate that underfilling of Disposable Urine Collection Tube containing preservative does not negatively impact the viability of urine microorganism. Sample panels were prepared by listed microorganisms (below) diluted from 1.5 x 10^8 CFU/mL (equivalent to a 0.5 McFarland standard) into the pooled human urine matrix to give a final concentration of 1.5 x 10^2 CFU/ml. Three production lots were tested in three replicates with each urine samples spiked with *E. coli, P. aeruginosa* or *P. mirabilis* at the sample fill volume of 90% and 110%. The inoculated sample tubes were initially tested to establish a time point zero then stored at 22-25ºC for 48 hrs. After the storage time, the samples were plated to grow colonies which were counted to determine CFU/ml for each time points. The acceptance criteria for the study is less than 1 $\log_{10}$ change when the fill volume is above or below the line. The results were shown in table 3.

Table 3. Performance of Disposable Urine Collection Tube in fill volume impact recovery study.

Strain tested	Fill volume	Average CFU/ml recovered (N=9) at time points		Change in Log_{10} (0 - 48 hrs)
		0 hr	48 hrs	
E. coli (ATCC 25922)	90%	125	48	-0.42
	110%	127	46	-0.44
P. aeruginosa (ATCC 27853)	90%	143	49	-0.47
	110%	142	50	-0.45
P. mirabilis (ATCC 7002)	90%	140	40	-0.54
	110%	139	39	-0.55

Fill volume recovery study results were acceptable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. 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 conducted to determine the ability of the Disposable Urine Collection Tube for urine collection, transport & preservation to maintain viability of microorganisms commonly found as the etiological agents of urinary tract infections. The analytical studies showed recovery of representative bacteria are within the acceptance criteria recommended in CLSI-M40-A2.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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