November 17, 2022

Zhejiang Gongdong Medical Technology Co., Ltd.
℅ Evan Hu
Marketing & Technical Manager
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, Shanghai 201114
China

Re: K220739
Trade/Device Name: Disposable Urine Collection Tube
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM, LIO
Dated: March 7, 2022
Received: March 14, 2022

Dear Evan Hu:

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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 866.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 866.9.

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
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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)*
K220739

Device Name
Disposable Urine Collection Tube

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

I. SUBMITTER:

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Date Prepared: November 9, 2022

II. DEVICE

Name of Device: Disposable Urine Collection Tube
Classification Name: Culture Media, Non-Propagating Transport
FDA Panel: Microbiology
Classification Number: 21 CFR 866.2390, Transport Culture Medium
Regulatory Class: Class I
Product Code: JSM, LIO

III. PREDICATE DEVICE

Primary predicate device: UriSwab™ - Urine Collection, Transport and Preservation System (K180052)
Classification Name: Culture Media, Non-Propagating Transport
FDA Panel: Microbiology
Classification Number: 21 CFR 866.2390, Transport Culture Medium
Regulatory Class: Class I
Product Code: JSM, LIO

IV. 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. Description and Packaging configurations of Disposable Urine Collection Tube

REF NO.	Draw volume (mL)	Tube size (Diameter × Length) in mm	Additive Boric acid in mg	Material	Type of tube	Cap colour
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

V. INDICATIONS FOR USE/INTENDED 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 clinical laboratory operating procedures for the cultivation of uropathogenic bacteria and yeasts.

VI. 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.

VII. COMPARISON WITH THE PREDICATE DEVICE

The device, Disposable Urine Collection Tube is compared with the predicate device UriSwab - Urine Collection, Transport and Preservation System (K180052). The results are shown below in the comparison table:

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		
Indications For Use	Disposable Urine Collection Tube is intended for the collection, transport, and preservation of	Copan UriSwab™ - Urine Collection, Transport and Preservation System is intended for the

	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.	collection, transport, and preservation of urine specimens from the collection site to the testing laboratory. In 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, **Sodium formate**
Collection device	PET tube with additive	Plastic tube, stick with sponge
Tube filling	Predefined vacuum	Sponge applicator

VIII. PERFORMANCE DATA

Analytical Performance

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 added to 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 stored at 2-4°C and 22-25°C for 24, 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 Microbial Recovery Results of Disposable Urine Collection Tube

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 (ATCC 15305)	2-4°C	139	109	69	-0.30
	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

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 negative clinical 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 stored at 22-25°C for 0 and 48 hrs. After each storage time, the samples were plated to grow colonies which were counted to determine CFU/ml for each time points. The acceptance criterium 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

IX. 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.

X. SHELF LIFE

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, following performance test were conducted:

Appearance, Vacuum, Leak testing, Strength test, 50Kpa Pressure Test, PET tube's mechanical stress testing, Sterility test, Standards of boric acid content, Package integrity

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 (measuring the boric acid content in the tube) 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.

The results for shelf-life study support that the Disposable Urine Collection Tube is physically or visually stable for 18 months.