August 29, 2024

Ensol Biosciences Inc.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K220908
Trade/Device Name: Ensol EnTM Specimen Collection and Transport System
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I, reserved
Product Code: JSM
Dated: October 30, 2023
Received: October 30, 2023

Dear Priscilla Chung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
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)*
K220908

Device Name
Ensol EnTM Collection and Transport System

Indications for Use *(Describe)*
The Ensol EnTM Collection and Transport System is intended for the collection and transportation of clinical samples containing upper respiratory viruses including Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus (RSV) from the collection site to the testing laboratory to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.

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: K220908

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 8/29/2024

Applicant / Submitter

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U.S. Designated Agent

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Trade/Proprietary Name:

Ensol EnTM Specimen Collection and Transport System

Common Name:

Viral Transport Medium (VTM)

Classification:

Non-propagating transport culture media (21CFR 866.2390, Product code JSM, Class 1, Microbiology)

Device Description:

The EnTM Collection and Transport System medium consists of a polypropylene conical tube filled with 2 ml of the transport medium (pale brown to red color medium solution), affixed with a polyethylene screw cap. The bottom part of the tube has a self-standing shape. Tubes are provided in a paper rack. The media tubes can be provided with one or two kinds of sterile specimen collection swabs, one for oropharyngeal (OP) oral use and the other nasopharyngeal (NP) for nasal use. The swab shaft is polystyrene with a breaking point, and the swab tip is flocked nylon fibers. The media is provided in two different configurations with and without the sterile peel pouch containing swabs as shown below:

Cat No.	Tube with VTM	Swab	Packaging
ES-TM-01	2 mL of VTM solution in 16 x 105 mm conical shape bottom screw-cap tube	One applicator NP swab with flocked nylon fiber tip with breaking point	50 tubes with culture medium per box 50ea, NP swabs 50ea. OP swabs

		One applicator throat swab with flocked nylon fiber tip with breaking point Both swabs packaged together in a sterilized peel pouch	
ES-TM-02	2 mL of VTM solution in 16 x 105 mm conical shape bottom screw-cap tube	No swabs	50 tubes with culture medium per box

Principle of Operation:

The EnTM Collection and Transport System is an osmotically balanced and buffered medium that contains Hank's balanced salt solution. Also, the medium contains a pH indicator, a protein stabilizer, sucrose as a preservative and antibiotics to prevent contamination from bacteria or fungi. The EnTM Collection and Transport System is used to safely collect and transport upper respiratory viruses from collection sites to the testing laboratories. It is intended to be used by health care professionals.

After collecting a specimen using the swab, the swab is placed into the uncapped polypropylene tube filled with 2 mL of the transport medium, the swab shaft is broken off at the breakpoint by hand and the tube is capped closed. The swab specimen can be stored in the collection medium for up to 48 hours at 4°C. The swab specimen is ready for use in diagnostic to determine the presence of a target pathogen. Sample collection is performed by health care professionals.

Indication for use:

The EnTM Collection and Transport System is intended for the collection and transportation of clinical samples containing upper respiratory viruses including Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus (RSV) from the collection site to the testing laboratory to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.

Predicate Device:

Copan Universal Transport Medium (UTM-RT) System (K042970) by COPAN DIAGNOSTICS, INC.

Substantial Equivalence:

The subject and predicate devices comparison is described in the table below:

Device and Predicate Device	**Device: K220908**	**Predicate: K042970**
Device Trade Name	EnTM Collection and Transport System	Copan Universal Transport Medium (UTM-RT) System
Device Product Code and Classification	JSM	JSM
General Device Characteristic Similarities		

Intended Use/Indications For Use	The EnTM Collection and Transport System is intended for the collection and transportation of clinical samples containing upper respiratory viruses including Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus (RSV) from the collection site to the testing laboratory to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.
Tube Material	Plastic	Same
Single Use Device	Yes	Same
Sterile Device	Yes	Same
Shelf Life	12 months	Same
General Device Characteristic Differences		
List of Ingredients	Modified Hank's Balanced Salts with calcium and magnesium ions Sucrose Bovine serum albumin HEPES Gelatin L-Cysteine L-Glutamic acid Gentamicin sulfate Amphotericin B Vancomycin Colistin sulfate salt Phenol Red sodium salt	Hank's Balanced Salts, Sucrose, Bovine serum albumin, HEPES Buffer Gelatin L-Cysteine L-Glutamic acid Amphotericin B Vancomycin Colistin Phenol Red
Samples Transported to Perform	Assays to detect the following upper respiratory viruses: Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus (RSV)	Assays to detect viruses, chlamydiae, mycoplasmas, or ureaplasmas
Specimen transport conditions and storage time	Specimen stored at 4ºC and processed within 48 hours	Specimen stored at 4 -25 ℃ and processed within 48 hours
Device Storage Temperature	25 ℃	2 -25 ℃

Shelf-life stability:

The shelf life for the EnTM Collection and Transport System was determined to be 12 months from the date of manufacture when stored at a temperature of 25℃. The shelf life of the EnTM Collection and Transport Medium was evaluated using real-time aging performance test.

Physical Stability: Physical stability was evaluated by Appearance, UV spectrum analysis (Scan: absorbance at 250-800 nm), and pH measurement at time points T = 0, 6, and 12 months using three lots stored at 25℃ and higher. The appearance was evaluated by inspecting visually to examine for a red and clear solution. Appearance results were acceptable. To detect any physical changes in the media, UV Spectrum analysis was conducted by setting the wavelength range to 250-800 nm (scan). The UV spectrum scanning analysis for 250-800 nm produced similar results for all lots at all storage times. Absorbance at 290 nm was also measured for any physical changes and results showed no

changes and produced similar results for all lots at all storage times. For pH measurement study, all the transport media demonstrated pH level within 7.4±1 for all lots at all storage times.

Sterility test: The EnTM Collection and Transport System is not claimed to be sterile nor is it intended to be sterilized by the end user. To reduce the contamination, the screw-cap tube is sterilized by irradiation with a maximum dose of 40 kGy using the E-beam irradiation process. A check for possible contamination was conducted by transferring transport media to growth medium Thioglycolate and incubated at 35 ºC for 3 days, and in Tryptic Soy Broth at 25ºC for 5 days and examined for growth turbidity. No bacterial or fungal proliferation was detected at either condition tested.

Culture-Based Viral Recovery Study:

Performance of the EnTM Collection and Transport System media was evaluated for virus viability at refrigerated temperatures (4 °C). Three lots of VTM with newly manufactured, middle-aged lot and close to expiry lots were used to evaluate viral recovery (ENTM-22001, ENTM-22003, and ENTM-23001). Influenza A (California/07/2009 H1N1, NCCP 42467), Human coronavirus 229E (Zeptometrix 0810229CF), and Human respiratory syncytial virus type A (type A strain Long, ATCC VR-26) were used for the viral recovery study. Each virus was diluted in pooled negative nasopharyngeal matrix transferred to the collection swab and then added to the Viral Transport Media. Aliquots of each replicate were stored at 4°C for 0, 24, and 48 hours. Host cells (MDCK for Influenza A, MRC-5 for Human coronavirus, and HEp-2 for Human respiratory syncytial virus type A) were plated for 1 day. At each timepoint the viral samples from EnTM were serially diluted and inoculated onto the host cell-line and cultured in a 96 well plate. The plates were incubated at 37°C and viral CPE was observed after 4-5 days. Viral titer was determined by the Reed-Muench method calculation of $TCID_{50}$ (50% tissue culture infective dose).

Results were considered acceptable if the average viral titer demonstrates any percent changes within ±90% (i.e.,1 log change). The results are presented in the Table 1. Any changes in the viral titer in the timepoints was shown as percent changes and negative percent change indicates reduction.

Table 1: Recovery of Viruses at 4˚C Storage.

Test Virus	Lot	Average Virus Titer ($TCID_{50}$/mL)			Percent Changes (0 to 24 hrs.)*	Percent Changes (0 to 48 hrs.)*
		0 hr	24 hrs.	48 hrs.		
Influenza A	ENTM-22001	3.58E+07	6.49E+06	9.07E+06	-81.84%	-74.64%
	ENTM-22003	2.80E+07	1.07E+07	1.33E+07	-61.70%	-52.53%
	ENTM-23001	3.34E+07	1.35E+07	6.04E+06	-59.53%	-81.89%
Human Coronavirus 229E	ENTM-22001	1.11E+04	1.16E+04	1.18E+04	3.73%	5.58%
	ENTM-22003	1.93E+04	2.36E+04	8.04E+03	22.25%	-58.41%
	ENTM-23001	1.14E+04	1.08E+04	8.87E+03	-5.69%	-22.36%
Respiratory Syncytial Virus	ENTM-22001	7.20E+05	5.20E+05	6.65E+05	-27.73%	-7.66%
	ENTM-22003	8.71E+05	4.05E+05	7.02E+05	-53.47%	-19.43%
	ENTM-23001	1.06E+06	3.72E+05	5.82E+05	-64.99%	-45.26%

*-ve indicates decline.

EnTM Collection and Transport System media demonstrated the recovery of viruses at 4˚C storage when evaluated for 48 hrs. in all replicates of tested viral strains (Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus). All the results support specimen transport for up to 48 hours when stored at 4˚C.

Conclusion:

The documentation submitted in this premarket notification demonstrates that the subject device K220908 has comparable features and performance and is substantially equivalent to the predicate device.