

K220908 Ensol EnTM Specimen Collection and Transport System

Aug 29, 2024
884 days to decisionK220908 · Product code: **JSM** · Microbiology
Source: <https://www.510kdatabase.net/k220908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Non-propagating Transport (JSM)
Date received	Mar 29, 2022
Decision date	Aug 29, 2024
Days to decision	884 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ensol Biosciences, Inc.
Location	Daejeon, KR
Contact	Cheol-Min Lee
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220908/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026