

K212856 iClean Viral Transport System (VTM-RT kit)Aug 18, 2022
344 days to decisionK212856 · Product code: **JSM** · Microbiology
Source: <https://www.510kdatabase.net/k212856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Non-propagating Transport (JSM)
Date received	Sep 8, 2021
Decision date	Aug 18, 2022
Days to decision	344 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huachenyang (Shenzhen) Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Robin Chu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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