

**K211707 BioTeke Sterile Disposable Virus Sampling Kit**May 4, 2022  
335 days to decisionK211707 · Product code: **JSM** · Microbiology  
Source: <https://www.510kdatabase.net/k211707/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Non-propagating Transport (JSM)
Date received	Jun 3, 2021
Decision date	May 4, 2022
Days to decision	335 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioteke Corporation (Wuxi) Co., Ltd.</b>
Location	Wuxi City, CN
Contact	Zhitu Zhou
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>QSR Consulting</b>
Contact	Kenneth Kleinhenz

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211707/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026