

K242767 Safecare Urinary Tract Infection TestJan 10, 2025
119 days to decisionK242767 · Product code: **JMT** · Chemistry
Source: <https://www.510kdatabase.net/k242767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo (colorimetric), Nitrite (urinary, Non-quant) (JMT)
Date received	Sep 13, 2024
Decision date	Jan 10, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Safecare Biotech (Hangzhou) Co., Ltd.
Location	Hangzhou, CN
Contact	Selina Zhang
510(k) history	9 submissions · 9 cleared · 2016-2025

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