

K203833 Tacrolimus Assay KitJan 27, 2023
758 days to decisionK203833 · Product code: **MLM** · Chemistry
Source: <https://www.510kdatabase.net/k203833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Tacrolimus (MLM)
Date received	Dec 30, 2020
Decision date	Jan 27, 2023
Days to decision	758 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Genext Medical Technology Co., Ltd.
Location	Shanghai, CN
Contact	Kimmy Zong
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Giselle Zhang

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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