

K181436 OSOM Mono TestJun 22, 2018
21 days to decisionK181436 · Product code: **KTN** · Microbiology
Source: <https://www.510kdatabase.net/k181436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Jun 1, 2018
Decision date	Jun 22, 2018
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary
Other names	Sure Vue Signature Mono; ImmunoCard STAT Mono; Cardinal Health Mono II Rapid Test

APPLICANT

Company	SEKISUI Diagnostics, LLC
Location	San Diego, CA, US
Contact	Shelly Harris
Website	https://www.sekisuidiagnostics.com
510(k) history	6 submissions · 6 cleared · 2012-2025

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