

K053135 SYSMEX UF-100I AUTOMATED URINE CELL ANALYZERJan 4, 2006
57 days to decisionK053135 · Product code: **LKM** · Pathology
Source: <https://www.510kdatabase.net/k053135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Urine Particle (LKM)
Date received	Nov 8, 2005
Decision date	Jan 4, 2006
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	NINA GAMPERLING
510(k) history	31 submissions · 31 cleared · 2003-2026

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