

K083002 SYSMEX UF-500I AUTOMATED URINE PARTICLE ANALYZERFeb 3, 2009
118 days to decisionK083002 · Product code: **LKM** · Pathology
Source: <https://www.510kdatabase.net/k083002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Urine Particle (LKM)
Date received	Oct 8, 2008
Decision date	Feb 3, 2009
Days to decision	118 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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