FDA 510(k) Premarket Notification

K012372 SYSMEX UF-50

K012372 · Product code: **LKM** · Pathology
Source: https://www.510kdatabase.net/k012372/

CLEARED

Sep 28, 2001
64 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Urine Particle (LKM)
Date received	Jul 26, 2001
Decision date	Sep 28, 2001
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sysmex Corp.**
Location	Mchenry, IL, US
Contact	CHRIS STUKEL
510(k) history	18 submissions · 18 cleared · 1979-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k012372/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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