FDA 510(k) Premarket Notification

K000373 939UDX URINE PATHOLOGY SYSTEM

CLEARED

Apr 14, 2000
70 days to decision

K000373 · Product code: **LKM** · Pathology
Source: https://www.510kdatabase.net/k000373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Urine Particle (LKM)
Date received	Feb 4, 2000
Decision date	Apr 14, 2000
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intl. Remote Imaging Systems**
Location	Mchenry, IL, US
Contact	HARVEY L KASDAN
510(k) history	14 submissions · 14 cleared · 1982-2002

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k000373/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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