

**K171883 Sysmex UF-5000 Fully Automated Urine Particle Analyzer**Apr 23, 2018  
304 days to decisionK171883 · Product code: **LKM** · Hematology  
Source: <https://www.510kdatabase.net/k171883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Urine Particle (LKM)
Date received	Jun 23, 2017
Decision date	Apr 23, 2018
Days to decision	304 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sysmex America, Inc.</b>
Location	Mundelein, IL, US
Contact	Sharita Brooks
510(k) history	30 submissions · 30 cleared · 2003-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171883/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026