

K182062 Sysmex UD-10, Fully Automated Urine Particle Digital Imaging Device

Oct 30, 2018
90 days to decision

K182062 · Product code: **JOY** · Hematology
Source: <https://www.510kdatabase.net/k182062/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Aug 1, 2018
Decision date	Oct 30, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	Jessica Rivera-Montejo
510(k) history	30 submissions · 30 cleared · 2003-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182062/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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