

K200754 Hemosure Accu-Reader A100Jun 2, 2022
801 days to decisionK200754 · Product code: **OOX** · Hematology
Source: <https://www.510kdatabase.net/k200754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Occult Blood Analyzer (OOX)
Date received	Mar 23, 2020
Decision date	Jun 2, 2022
Days to decision	801 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	W.H.P.M., Inc.
Location	Beverly, MA, US
Contact	Farokh Etemedieh
510(k) history	14 submissions · 14 cleared · 2001-2022

REGULATORY CONSULTANT

Consulting firm	Smith Associates
Contact	Farokh Etemadieh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200754/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026