FDA 510(k) Premarket Notification

K200754 Hemosure Accu-Reader A100

CLEARED

Jun 2, 2022
801 days to decision

K200754 · 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