

K242388 LensHooke X12 PRO Semen Analysis SystemMay 9, 2025
270 days to decisionK242388 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k242388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Aug 12, 2024
Decision date	May 9, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bonraybio Co., Ltd.
Location	Taichung, TW
Contact	Clare Huang
510(k) history	5 submissions · 5 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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