

**K242830 LensHooke X3 PRO Semen Quality Analyzer**May 30, 2025  
253 days to decisionK242830 · Product code: **POV** · Hematology  
Source: <https://www.510kdatabase.net/k242830/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Sep 19, 2024
Decision date	May 30, 2025
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	LensHooke X3 PRO SE Semen Quality Analyzer

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242830/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026