

**K180343 LensHooke X1 Pro Semen Quality Analyzer,  
 LensHooke X1 Semen Quality Analyzer**

Nov 16, 2018  
 282 days to decision

K180343 · Product code: **POV** · Hematology  
 Source: <https://www.510kdatabase.net/k180343/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Feb 7, 2018
Decision date	Nov 16, 2018
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

**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/k180343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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