

**K202089 LensHooke X1 PRO Semen Quality Analyzer,
 LensHooke X1 PRO SE Semen Quality Analyzer**

Oct 28, 2020
 92 days to decision

K202089 · Product code: **POV** · Hematology
 Source: <https://www.510kdatabase.net/k202089/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Semen Analysis Device (POV)
Date received	Jul 28, 2020
Decision date	Oct 28, 2020
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202089/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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