

K221810 LensHooke CA1 Sperm Separation Device, LensHooke CA0 Sperm Separation DeviceOct 31, 2022
131 days to decisionK221810 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k221810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Jun 22, 2022
Decision date	Oct 31, 2022
Days to decision	131 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

REGULATORY CONSULTANT

Consulting firm	Ivdd Regulatory Consultant
Contact	Feng-Yu Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221810/>; Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026