

K242684 Harioculture TL-16 Time-lapse IncubatorMay 22, 2025
258 days to decisionK242684 · Product code: **MQG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k242684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Assisted Reproduction (MQG)
Date received	Sep 6, 2024
Decision date	May 22, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hua Yue Medical Technology Co., Ltd.
Location	Guangzhou, CN
Contact	Zhenzhi Shi
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242684/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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