

K253333 Assisted Reproduction Laser System (Model ILS-400M)Jun 17, 2026
260 days to decisionK253333 · Product code: **MRX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k253333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Assisted Reproduction Laser (MRX)
Date received	Sep 30, 2025
Decision date	Jun 17, 2026
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hua Yue Medical Technology Co., Ltd.
Location	Guangzhou, CN
Contact	Zhenzhi Shi
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253333/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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