

**K232493 Embryo Real-time Incubator (TLS301), Embryo Real-time Culture Dish (MC 2004)**May 7, 2024  
264 days to decisionK232493 · Product code: **MQG** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k232493/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Assisted Reproduction (MQG)
Date received	Aug 17, 2023
Decision date	May 7, 2024
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wuhan Huchuang Union Technology Co., Ltd.</b>
Location	Wuhan, CN
Contact	Yuanyuan Zhan
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov