

**K253354 Minvitro Embryo Transfer Catheters (ETCA23175, ETCA23175-C, ETCB20175, ETCB20175-C, ETCB20175-ET, ETCB20175-ET-C)**Feb 12, 2026  
135 days to decisionK253354 · Product code: **MQF** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k253354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Sep 30, 2025
Decision date	Feb 12, 2026
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangzhou Hehong Biotech Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Yu Feng
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253354/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026