FDA 510(k) Premarket Notification

K250838 Denudation Pipettes

CLEARED

Jul 3, 2025
105 days to decision

K250838 · Product code: **MQH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k250838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microtools, Assisted Reproduction (pipettes) (MQH)
Date received	Mar 20, 2025
Decision date	Jul 3, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guangzhou Pinzhi Medical Device Co., Ltd.**
Location	Guangzhou, CN
Contact	Hestia Xu
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Chonconn Consulting Co., Ltd.**
Contact	Jie Yang

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