FDA 510(k) Premarket Notification

K252899 Female Culture Device

CLEARED

Jun 2, 2026
264 days to decision

K252899 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k252899/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Sep 11, 2025
Decision date	Jun 2, 2026
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Male Culture Device; Transfer Device; Access Device

APPLICANT

Company	**Zhejiang Kindly Medical Device Co., Ltd.**
Location	Wenzhou City, CN
Contact	Qian Zhang
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mind-Link Consulting Co., Ltd.**
Contact	Evan Hu

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