

K220576 FAMA Male Latex CondomsAug 5, 2022
158 days to decisionK220576 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k220576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Feb 28, 2022
Decision date	Aug 5, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Personage Hygiene Products Co., Ltd.
Location	Qingpu District, CN
Contact	Haijiang Song
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Medwheat, Inc.
Contact	Vincent Zhou

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220576/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026