

K232957 Sterile and Non-Sterile Ultrasound GelsDec 15, 2023
85 days to decisionK232957 · Product code: **MUI** · Radiology
Source: <https://www.510kdatabase.net/k232957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Sep 21, 2023
Decision date	Dec 15, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jianerkang Medical Co., Ltd.
Location	Changzhou, CN
Contact	Zhang Zhigang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Suzhou Device Innovation Medical Consulting Co., Ltd.
Contact	Gu Mike

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/k232957/> 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 25, 2026