

K242167 Sterile and Non-Sterile Ultrasonic Coupling AgentSep 19, 2024
57 days to decisionK242167 · Product code: **MUI** · Radiology
Source: <https://www.510kdatabase.net/k242167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Jul 24, 2024
Decision date	Sep 19, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Deepblue Medical Technology Co., Ltd.
Location	Hefei, CN
Contact	Fengling Chen
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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