FDA 510(k) Premarket Notification

K221999 Ultrasound Transmission Gels

CLEARED

Aug 30, 2022
54 days to decision

K221999 · Product code: **MUI** · Radiology
Source: https://www.510kdatabase.net/k221999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Jul 7, 2022
Decision date	Aug 30, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hony Medical Co., Ltd.**
Location	Taishan, CN
Contact	Zhu Huina
510(k) history	4 submissions · 4 cleared · 2022-2024

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