FDA 510(k) Premarket Notification

K241789 Non-Sterile Ultrasound Transmission Gels

CLEARED

Jul 24, 2024
33 days to decision

K241789 · Product code: **MUI** · Radiology
Source: https://www.510kdatabase.net/k241789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Jun 21, 2024
Decision date	Jul 24, 2024
Days to decision	33 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	Wang Boyle

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