FDA 510(k) Premarket Notification

K241996 ULTRA 1040

CLEARED

Apr 18, 2025
283 days to decision

K241996 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k241996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 9, 2024
Decision date	Apr 18, 2025
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ecoray Co., Ltd.**
Location	Seoul, KR
Contact	Haeri Lee
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Mansour Consulting, LLC**
Contact	Jay Mansour

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