FDA 510(k) Premarket Notification

K240759 REMEX-GR100

CLEARED

May 13, 2024
54 days to decision

K240759 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k240759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Mar 20, 2024
Decision date	May 13, 2024
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Remedi Co., Ltd.**
Location	Seoul, KR
Contact	Sungho Cho
510(k) history	3 submissions · 3 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**510K FDA, Inc.**
Contact	Lee Strong

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