

K213405 MINE ALNU (Model: Mine 2.1)Jul 10, 2022
264 days to decisionK213405 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k213405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Oct 19, 2021
Decision date	Jul 10, 2022
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hdt Co., Ltd.
Location	Gwangju, KR
Contact	Sung Hee Chun
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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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