

K213520 AXIR-CXAug 19, 2022
289 days to decisionK213520 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k213520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 3, 2021
Decision date	Aug 19, 2022
Days to decision	289 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Radisen Co., Ltd.
Location	Anyang-Si, KR
Contact	John Lim
510(k) history	2 submissions · 2 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

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