FDA 510(k) Premarket Notification

K213520 AXIR-CX

CLEARED

Aug 19, 2022
289 days to decision

K213520 · 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