FDA 510(k) Premarket Notification

K223125 XR90 (XR90-SYS)

K223125 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k223125/

CLEARED

Jul 13, 2023
283 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 3, 2022
Decision date	Jul 13, 2023
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mediview Xr, Inc.**
Location	Cleveland, OH, US
Contact	Adam Cargill
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223125/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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