

K213660 RadAllyMar 31, 2023
494 days to decisionK213660 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k213660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 22, 2021
Decision date	Mar 31, 2023
Days to decision	494 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imaging Wave, LLC
Location	Forrest Hills, NY, US
Contact	Edward Kantor
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213660/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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