

K223133 VisiRad XRAug 3, 2023
304 days to decisionK223133 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k223133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Oct 3, 2022
Decision date	Aug 3, 2023
Days to decision	304 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imidex, Inc.
Location	Denver, CO, US
Contact	Kris Zeschin
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223133/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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