FDA 510(k) Premarket Notification

K223133 VisiRad XR

CLEARED

Aug 3, 2023
304 days to decision

K223133 · 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