

K212587 3D-RD-SFeb 22, 2023
555 days to decisionK212587 · Product code: **IYX** · Radiology
Source: <https://www.510kdatabase.net/k212587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Aug 16, 2021
Decision date	Feb 22, 2023
Days to decision	555 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Radiopharmaceutical Imaging and Dosimetry, LLC
Location	Baltimore, MD, US
Contact	Nadine Bonds
510(k) history	1 submissions · 1 cleared · 2023-2023

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