

K213353 Aorta-CADSep 20, 2022
347 days to decisionK213353 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k213353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Oct 8, 2021
Decision date	Sep 20, 2022
Days to decision	347 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imagen Technologies, Inc.
Location	New York, NY, US
Contact	Robert Lindsey
510(k) history	6 submissions · 5 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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