

K230085 Lung-CADOct 3, 2023
265 days to decisionK230085 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k230085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Jan 11, 2023
Decision date	Oct 3, 2023
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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