FDA 510(k) Premarket Notification

K210666 Chest-CAD

CLEARED

Jul 20, 2021
137 days to decision

K210666 · Product code: **MYN** · Radiology
Source: https://www.510kdatabase.net/k210666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Mar 5, 2021
Decision date	Jul 20, 2021
Days to decision	137 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.net
Device record: https://www.510kdatabase.net/k210666/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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