

K203258 syngo.CT Lung CADMar 31, 2021
146 days to decisionK203258 · Product code: **OEB** · Radiology
Source: <https://www.510kdatabase.net/k203258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lung Computed Tomography System, Computer-aided Detection (OEB)
Date received	Nov 5, 2020
Decision date	Mar 31, 2021
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare GmbH
Location	Erlangen, DE
Contact	Abhineet Johri
510(k) history	30 submissions · 30 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203258/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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