FDA 510(k) Premarket Notification

CLEARED

K162484 Lung Nodule Assessment and Comparison Option (LNA)

Feb 23, 2017
169 days to decision

K162484 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k162484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 7, 2016
Decision date	Feb 23, 2017
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems Nederland B.V.**
Location	Best, NL
Contact	Yoram Levy
510(k) history	103 submissions · 102 cleared · 2005-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162484/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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