FDA 510(k) Premarket Notification

K162025 IntelliSpace Portal Platform

CLEARED

Oct 18, 2016
88 days to decision

K162025 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k162025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 22, 2016
Decision date	Oct 18, 2016
Days to decision	88 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems Nederlands B.V.**
Location	Best, NL
Contact	Ilana Ben Moshe
510(k) history	8 submissions · 8 cleared · 2015-2024