

K244016 iPETcertum (v1.0)Aug 5, 2025
221 days to decisionK244016 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k244016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 27, 2024
Decision date	Aug 5, 2025
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Claritas Healthtech Pte, Ltd.
Location	Singapore, SG
Contact	Devika Dutt
510(k) history	3 submissions · 3 cleared · 2021-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k244016/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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