

K213140 Claritas iPETDec 22, 2021
86 days to decisionK213140 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k213140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 27, 2021
Decision date	Dec 22, 2021
Days to decision	86 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/k213140/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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