

K212074 ClariCT.AI

Jul 27, 2021
25 days to decision

K212074 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k212074/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 2, 2021
Decision date	Jul 27, 2021
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Claripi, Inc.
Location	Seoul, KR
Contact	Hyun-Sook Park
510(k) history	4 submissions · 4 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	Claripi USA, Inc.
Contact	Harry Park

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov
