FDA 510(k) Premarket Notification

K203783 ClariPulmo

CLEARED

Apr 6, 2022
464 days to decision

K203783 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k203783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 28, 2020
Decision date	Apr 6, 2022
Days to decision	464 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 Detroit Office**
Contact	Harry Park

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