FDA 510(k) Premarket Notification

K203785 ClariSIGMAM

CLEARED

Sep 10, 2021
256 days to decision

K203785 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k203785/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 28, 2020
Decision date	Sep 10, 2021
Days to decision	256 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