

**K203785 ClariSIGMAM**Sep 10, 2021  
256 days to decisionK203785 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k203785/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Claripi Detroit Office</b>
Contact	Harry Park

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203785/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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