

**K212550 Hura CTP v1.0**Nov 8, 2021  
87 days to decisionK212550 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k212550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 13, 2021
Decision date	Nov 8, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hura Imaging, Inc.</b>
Location	Calabasas, CA, US
Contact	Danny Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Rook Quality Systems, Inc.</b>
Contact	Andrew Wu

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/k212550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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