

**K212758 Autoplaque**May 19, 2023  
626 days to decisionK212758 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k212758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 31, 2021
Decision date	May 19, 2023
Days to decision	626 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cedars-Sinai Medical Center: Aim</b>
Location	Los Angeles, CA, US
Contact	Damini Dey
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hyman, Phelps &amp; McNamara, P.C.</b>
Contact	Philip J.H. Won

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

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