FDA 510(k) Premarket Notification

K212758 Autoplaque

CLEARED

May 19, 2023
626 days to decision

K212758 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k212758/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hyman, Phelps & McNamara, P.C.**
Contact	Philip J.H. Won

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