

**K242240 CaRi-Plaque**Feb 20, 2025  
205 days to decisionK242240 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k242240/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 30, 2024
Decision date	Feb 20, 2025
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Caristo Diagnostics , Ltd.</b>
Location	Oxford, GB
Contact	Frank Cheng
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John Smith

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

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