

**K243863 Oplus™ Lymphoma Precision**May 30, 2025  
164 days to decisionK243863 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k243863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 17, 2024
Decision date	May 30, 2025
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	Aarti Shukla
510(k) history	49 submissions · 46 cleared · 1993-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243863/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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