FDA 510(k) Premarket Notification

# K243863 Opulus™ Lymphoma Precision

**CLEARED**

May 30, 2025
164 days to decision

K243863 · 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

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