

K250766 LungQ 4Oct 2, 2025
203 days to decisionK250766 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k250766/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | Mar 13, 2025 |
| Decision date | Oct 2, 2025 |
| Days to decision | 203 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Thirona BV |
| Location | Toernooiveld 300, NL |
| Contact | Eva van Rikxoort |
| 510(k) history | 2 submissions · 2 cleared · 2024-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250766/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026