

**K250414 CaloPix**May 14, 2025  
90 days to decisionK250414 · Product code: **QKQ** · Pathology  
Source: <https://www.510kdatabase.net/k250414/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Digital Pathology Image Viewing And Management Software (QKQ) |
| Date received         | Feb 13, 2025  |
| Decision date         | May 14, 2025  |
| Days to decision      | 90 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Tribun Health</b>                  |
| Location       | Paris, FR                             |
| Contact        | Jean-François Pomerol                 |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250414/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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