

**K231420 Aura 10 PET/CT**Aug 10, 2023  
86 days to decisionK231420 · Product code: **QXL** · Radiology  
Source: <https://www.510kdatabase.net/k231420/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cabinet, Emission Computed Tomography System (QXL)
Date received	May 16, 2023
Decision date	Aug 10, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xeos Medical</b>
Location	Gent, BE
Contact	Bjorn Delbeecke
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231420/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026