

**K231576 cNeuro cPET**Sep 14, 2023  
106 days to decisionK231576 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k231576/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	May 31, 2023
Decision date	Sep 14, 2023
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Combinostics OY</b>
Location	Tampere, FI
Contact	Thurfjell Lennart
510(k) history	3 submissions · 3 cleared · 2018-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Erin Gontang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231576/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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